UNITED STATES DISTRICT COURT

FOR THE DISTRICT OF ARIZONA

IN RE: Bard IVC Filters Products Liability Litigation,	)	MD 15-02641-PHX-DGC
Lisa Hyde and Mark Hyde, a married couple,	)	Phoenix, Arizona **September 25, 2018**
Plaintiffs,	)	
v.	)	CV 16-00893-PHX-DGC
C.R. Bard, Inc., a New Jersey corporation, and Bard Peripheral Vascular, an Arizona corporation,	)	
Defendants.	)	

BEFORE: THE HONORABLE DAVID G. CAMPBELL, JUDGE

REPORTER'S TRANSCRIPT OF PROCEEDINGS

TRIAL DAY 6 - A.M. SESSION

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Proceedings Reported by Stenographic Court Reporter
Transcript Prepared with Computer-Aided Transcription

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I N D E X

EXAMINATION

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EXHIBITS

P R O C E E D I N G S

(Proceedings resumed in open court outside the presence of the jury.)

08:31:22 THE COURT: Thank you. Please be seated.

Morning, folks.

FOLKS: Morning, Your Honor.

THE COURT: What matters would you like to raise this morning?

08:30:37 MR. ROGERS: Your Honor, the defendants have a number of matters that relate to witnesses who will appear today and also, I believe, the deposition that's going to be, or scheduled to be, played for today that we would like to address.

08:30:50 THE COURT: All right.

MS. HELM: Your Honor, I'll start with the deposition.

THE COURT: You need a mic, Ms. Helm.

MS. HELM: I'm so sorry. You would think by now I 08:31:00 would remember. I apologize.

I'll start with the deposition. Mr. Fermanich is the sales representative that was involved in the two e-mail exchanges that Mr. Hug was asked about.

We have two issues. One, we want to make sure the 08:31:19 exhibits, to the extent they're displayed in the deposition,

are only displayed consistent with the Court's ruling on the hearsay objections to those two exhibits.

And the other issue is there's about 14 lines of -- it's really questioning in the deposition that we believe should be taken out because it reveals the hearsay that you've excluded. And we've -- we've discussed this and have not been able to reach an agreement.

I have the 14 lines identified. It's basically the questioner, the lawyer asking the questions of Mr. Fermanich, he's reading the hearsay.

I believe it can still be done where Mr. Fermanich can testify to what's -- what he -- what he said in the e-mails without the hearsay coming in through the questioner's question.

THE COURT: All right. What are the other issues?

MS. HELM: Your Honor, based on the exhibits that were provided to us, or identified to us for Mr. Van Vleet and Mr. Modra, the issue of the complaint files and the monthly management reports and the Rule 1006 summary appear to be today. They have identified about ten different complaint files and a handful of monthly management reports as exhibits, as well as the summary. We have not addressed that on the record previously and we need to address that.

And then with Mr. Modra, they have identified the FDA warning letter as an exhibit. So we're going to have to

address that as well.

THE COURT: Well, my view on those issues is I'm going to rule the same way I did in the last trials on those. So you ought to be able to work that out.

We went through the complaint files. I decided what I would allow in, what I wouldn't. We've been through the FDA warning letter twice and let in the same amount. So you ought to be able to work that out because I'm going to have the same view on those issues I did in the last trials.

MS. HELM: I understand that, Your Honor. As to the complaint files and monthly management reports, we would like to make sure we have a record in this case. So at the appropriate time I would like to make -- I understand your ruling, but I feel compelled that I need to make the record --

THE COURT: That's fine.

MS. HELM: -- in this case.

THE COURT: That's fine. You can make it whenever you choose. You can put it on the record orally. You can file a written statement. You absolutely can preserve the record as you choose to.

MS. HELM: Thank you, Your Honor.

THE COURT: Let me ask you this, Ms. Helm: I take it, then, that the record you want to make is an objection to the way we did it before; is that right?

08:33:59 MS. HELM: Yes, Your Honor. I want to preserve the objection to the complaint files and the monthly management reports and to the summary on the grounds that we asserted before. I'm not raising any new issues.

08:34:11 THE COURT: Okay.

MS. HELM: But I do think I need to make my record on that issue.

THE COURT: I agree. You can make your record. We'll go forward with the same evidence we did before.

08:34:20 MS. HELM: And, Your Honor, your ruling on the warning letter previously, as I understood it, was you would wait and see on the evidence to make a determination of when you under- -- when you thought it had become relevant in the case.

08:34:36 THE COURT: Well, that's what I did, I think, in the first trial. I can't remember if I did that in the second trial.

I came out the same place in both trials as to the portions that could be shown to the jury, I think.

08:34:52 MS. HELM: Yes, Your Honor. But we believe it's premature. It's not ready yet. As I recall your ruling in both Booker and in Jones, it took evidence, certain evidence, to be in the record before you found it was relevant. And, again, we've all been through a lot, but as I recall, in

08:35:12 Jones it was tendered a couple times and you kept saying no,

not yet, not yet.

THE COURT: Well, yeah, that was because I didn't understand yet whether it would be relevant. It wasn't so much as I wanted the evidence to come in in a particular order in the trial.

Having been through this twice, I think the same information is relevant, so I don't think I need to wait to rule on that in this trial.

MS. HELM: Okay. Thank you, Your Honor.

THE COURT: Those are the only issues?

MS. SMITH: Can I address two issues?

THE COURT: Well, yeah.

That's it, Ms. Helm?

MR. ROGERS: That's everything for witnesses for today, Your Honor.

THE COURT: Okay. Then let's go ahead and address -- let's address the Fermanich deposition issues.

MS. SMITH: First and foremost, defendants have not provided us with what they wanted to withdraw from this deposition, they've only said it was at issue.

And second --

THE COURT: Hold on.

Ms. Helm, have you given them the lines you think should be taken out?

MS. HELM: Actually, she identified the lines to me,

08:36:11 Your Honor. But they are 2 of --

THE COURT: Well, you all ought to talk about this and see if you have a disagreement.

MS. SMITH: We are in disagreement.

08:36:22 THE COURT: You are?

MS. HELM: I was told we were in disagreement and that I needed to raise it this morning.

MS. SMITH: Yes, but this is the first I've heard of the line, so I actually still don't know what lines are at

08:36:31 issue. But I can tell you what I think relates to the testimony and that, if you'll recall, on the e-mail it was actually to Fermanich. It was Mary Starr's e-mail in response to Fermanich, who is the individual that was at the deposition testifying to it. So he has first-hand knowledge

08:36:44 of his response and his present sense impression when he received it, which is what he's testifying to.

THE COURT: Well, but did the questioner read the portions I have said are inadmissible?

MS. SMITH: It's a summary of it. There's not a

08:36:58 direct quote.

THE COURT: Well, but what the questioner is saying is "in this document she says" and she summarizes it?

MS. SMITH: Well, what he's saying is they were -- he's replying to "You knew that a customer was still using

08:37:12 the G2, that it was still in stock."

08:37:15 And he's saying "Yes, I did." He's looking at the e-mail and saying yes, this is what -- this is the information I received when I read this e-mail.

THE COURT: Well, I've got to see it to see if I
08:37:24 think it presents the same hearsay problem.

MS. SMITH: Yeah. I have the testimony pulled up here.

Kate, what are the lines you're looking at?

THE COURT: Well, let's -- hold on. Hold on just a
08:37:35 minute. Let's do this in order.

Are you going to argue this morning, as you suggested, Mr. O'Connor, that I should let in the whole e-mail? Because if I agree with you on that, that eliminates this issue.

08:37:48 MS. SMITH: Yes, that's the intent, because now -- we tried get in with Mr. Hug and were unsuccessful. That here, because they address it also in his deposition and he is -- he's in this correspondence, the individual who is testifying, that it's represented and that we don't believe
08:38:06 there should be hearsay objection. And defendants also didn't bring this up when we did the depo submission.

THE COURT: Well, what is it about the fact that he's testifying that solves the hearsay problem?

MS. SMITH: I would say then it's not hearsay. It
08:38:20 was his present sense impression regarding it.

08:38:25 MR. O'CONNOR: Well, Your Honor, if I may?
THE COURT: Well, hold on a minute.
His present sense impression --
MS. SMITH: It's Mary's. When she responds to it.
08:38:34 THE COURT: Well, I think that's a stretch to use present sense impression on that argument. That would allow in any document that's written on the basis of what the person is thinking at the time. That's not present sense impression. It's when a person is perceiving something and
08:38:50 describes it, that's present sense impression.
Any writer ever writing what they're thinking would be a present sense impression if you're right, and that would mean we have no hearsay.
MR. O'CONNOR: Is that the testimony they're
08:39:01 objecting to?
MS. SMITH: Yes. I believe this whole --
Kate, what are the lines?
MS. HELM: 202/17 to 22 --
MR. O'CONNOR: If I may?
08:39:10 THE COURT: Yeah.
MR. O'CONNOR: The questions were directed to him about his knowledge. I can give you an example of it.
THE COURT: Mr. O'Connor, are we going to address the exhibits or are you not going forward with your arguments
08:39:20 about the exhibits?

08:39:23 MS. SMITH: So currently the testimony is coming in separately from the exhibit because --

THE COURT: I want to start at the exhibits.

Last night you told me you were going to do more
08:39:31 research and you were going to come this morning with cases to show me why the two exhibits are not hearsay. If you're not doing that, that's fine, let's talk about the testimony. But if you're going to do that and I agree with you, that solves this whole problem because the entire exhibit comes
08:39:45 in.

MR. O'CONNOR: Can't we do this and hold off on those exhibits until we show the judge the case law?

MS. SMITH: Sure.

MR. O'CONNOR: He knows about --

08:39:57 THE COURT: Okay. So you don't want to make the exhibits argument now; is that right?

MS. SMITH: Correct.

THE COURT: Okay. Then I do need to rule on the actual testimony.

08:40:06 So, yeah, we do need to talk about what it is they're objecting to in the testimony.

What I need is I need the exhibits in front of me and I need the testimony so I can see what's being said about them so I can decide if the testimony is admissible. Have
08:40:23 you got the transcript and exhibits so I can look at it?

08:40:26 MS. SMITH: I have it on laptop, I don't have it printed. This is the testimony.

THE COURT: You've got the exhibits; right?

MS. SMITH: Do you have a hard copy?

08:40:31 MS. HELM: Has my handwriting all over it.

MR. LOPEZ: You mean now, Judge? Want to do that now?

THE COURT: Well, when are you going to play Fermanich?

08:40:42 MS. SMITH: We'd like to play it today.

THE COURT: When?

MR. LOPEZ: We can do it this afternoon.

MS. SMITH: We can do it this afternoon.

THE COURT: Why don't we do this, then: If you'll

08:40:48 get me at lunch the two exhibits and the language from the deposition that they're objecting to highlighted, I'll hold the exhibits in one hand and the transcript in the other and I'll go through and decide whether or not I think the questioning is improper hearsay. And I'll rule at the end of

08:41:06 the lunch hour and then you can play it later in the afternoon taking into account my ruling. Does that work?

MS. SMITH: Yes.

THE COURT: Okay. Let's do that.

MR. LOPEZ: Actually, Judge, we may have another one

08:41:21 for you to do as well at that time, so we'll get them both to

08:41:25 you. There's another deposition where we cut it way back and there's an issue whether or not their counters go beyond the scope of where we cut our designations.

THE COURT: Okay.

08:41:34 MR. LOPEZ: We'll put them side by side so you can take a look at them.

THE COURT: That's fine. I'll look at those at the lunch hour.

Are there other matters plaintiff wants to raise?

08:41:44 MR. LOPEZ: Your Honor, I think we're prepared to address the issue we talked about yesterday on the aggressive marketing.

THE COURT: Okay.

MR. LOPEZ: First of all, Your Honor, we read the -- 08:42:01 I'm not sure how to pronounce the name *Kehl* or *Kehl* case.

THE COURT: I did too.

MR. LOPEZ: I don't think there's any semblance of relevance to that case. We're talking about the parties stipulating that the fleeing the scene did not contribute to 08:42:18 damages. Here, we're saying aggressive marketing clearly did.

And I think I probably should give you the exact -- you've only seen that little snippet of this -- of the aggressive marketing document.

08:42:32 May I -- may I approach, Your Honor?

08:42:34 THE COURT: Yes.

MR. LOPEZ: This is Exhibit 1053.

THE COURT: Have you got a copy for Plaintiffs' counsel? I mean defense counsel.

08:42:53 MR. LOPEZ: So let me -- before we get to the exhibit -- well, we can talk about it.

This exhibit is really a design document. It's -- when you look at -- this predated the launch of the Recovery filter. It's called a Product Opportunity Appraisal Form.

08:43:13 And actually it describes in here the design features of this new device that they're going to market.

And in the absence of testing -- the absence of testing the product and making sure that there's no clinical problems with it, they then start describing aggressive

08:43:39 marketing that can be used to get around the fact that the testing does not exist for the design they're developing. So this thing is all --

THE COURT: Where is that?

MR. LOPEZ: Hope I didn't give you my -- if you look

08:43:54 at page 004 right in the middle there. It says customer --

THE COURT: Hold on just a minute.

Looks like this is out of order.

MR. LOPEZ: Let me give you the actual copy of it. And I can take that one and struggle with it.

08:44:23 THE COURT: Okay. I'm on page --

08:44:25 MR. LOPEZ: Look at 00 --

THE COURT: Okay. 004.

MR. LOPEZ: Can we get -- I don't have the full document.

08:44:45 THE COURT: Let's make it --

MR. LOPEZ: I have it upside down.

THE COURT: Let's make it a basic practice that whenever we're going to talk about an exhibit, that we bring three copies.

08:44:57 MR. LOPEZ: Right. You know what we did, Judge. It's me. It's double sided. I had it upside down. Meaning I was starting on the last page.

So if you look at page 4 of the exhibit, customer requirements --

08:45:14 THE COURT: Right.

MR. LOPEZ: -- includes performance, physical requirements, safety considerations, price tolerance, packaging requirements, special requirements for international markets and desired marketing claims.

08:45:25 And then the first point under there, under filter, must be designed so that it can be safely removed after an extended period of indwelling time. And it gives all the safety features -- all the safety features and the design of the product right there. It says it must resist migration, 08:45:41 exhibit minimal tilting within the vena cava. Then it talks

08:45:45 about the delivery system and the packaging. And, of course, it describes the device on that page.

And then the next page, page 5, talks about the competitive analysis of this new product and its design and
08:46:03 it talks about the patent. I won't read all of this, but I'm just doing this to show you that this document is just not a marketing document. It, in fact, is a document about the new design of this device.

Then page 6 and 7 do the same thing.

08:46:21 And we get to the language in question. Then it goes through, you know, how they're going to position this thing.

I don't have the right document here, guys.

I apologize, Your Honor. I think I gave you -- I
08:47:06 don't have the page that has the aggressive marketing --

THE COURT: Do you want to get this back and look at it?

(Mr. Mankoff and Mr. Lopez confer.)

MS. SMITH: It's on the screen, Ramon.

08:47:40 MR. LOPEZ: I need the page that has the aggressive marketing statement we've been talking about. It's on this page?

I'm sorry, Judge. It actually is on my copy.

If you look at the top part of 004, the following
08:47:59 points summarize the current IVC filter market and project --

08:48:04 and project the future trends. And that's the language that we've lifted out of and cross-examined Ms. Hudnall on, and that is users can be swayed by ease of use. That's a design feature. Low profile. That's a design feature. And
08:48:23 aggressive marketing. Even in the absence of solid clinical history. And that's, of course, negligent design whether or not they've tested it properly. And in spite of documented negative clinical experiences.

So here we have a document that clearly goes to the
08:48:44 fact that intertwined, and maybe in the lack of design features, the company's saying that they can get around that with aggressive marketing even if they haven't tested it and even if they don't have solid clinical history.

You know one of our claims here is they should have
08:49:00 had clinical trials in this case. This should have been a long-term clinical trial.

The utilization of aggressive marketing in order to sway the user from lack of clinical testing experience is relevant to Plaintiff Hyde's negligent design defect claim
08:49:19 where the language of the jury instructions includes, quote, it is the further duty of the manufacturer in the exercise of ordinary care to make all reasonable and adequate tests and inspections of its product so as to guard against any defective condition which would render such product unsafe.

08:49:39 Also, aggressive marketing techniques in the context

08:49:42 of the document that we've been talking about and the testimony about that document from I think Ms. Hudnall for one and maybe others is relevant to plaintiffs' negligent design defects claim and is also relevant to punitive damages
08:49:55 in that such conduct, that is engaging in aggressive marketing to avoid reasonable and adequate testing, could be deemed by a jury to be substantially certain to result in plaintiffs' rights being disregarded.

If there is no compensatory award for negligent
08:50:13 design based on the factors described in this jury instruction, I think it's a pattern jury instruction 3240, then there can be no punitive damages for that cause of action.

So there's nothing about the aggressive marketing
08:50:26 described in this trial exhibit that's unrelated to the design and development of the first IVC filter. I mean, it's all intertwined with things regarding the design and the testing and whether or not there's clinical evidence that could get them away from -- or defending the negligent design
08:50:44 claim in this case, Your Honor.

THE COURT: Okay.

MR. LOPEZ: I'll give you the document so you can see it in context of the discussion about that.

THE COURT: All right. And this is the language you
08:51:00 want to present as part of the Hudnall deposition excerpt --

08:51:04 MR. LOPEZ: Right.

THE COURT: -- correct?

MR. LOPEZ: Yes, sir. And there are other parts of this document we do walk her through in her deposition, but I 08:51:11 think that may be the only one you've ruled against.

THE COURT: Okay.

Defendants.

MR. ROGERS: Your Honor, several points on that. First of all, the document, the Product Opportunity 08:51:28 Appraisal, as I'm sure the Court could see, is a document from 2005, and it relates to the IVC market prior to the introduction of the Recovery filter.

And, Your Honor, I would submit to the Court that that is six years before Mrs. Hyde received her filter, about 08:51:48 a different era, different product, and there's no causal connection between that and whatever the market was doing and whatever the marketing strategy was at the time that Mrs. Hyde's filter was implanted.

Secondly, Your Honor, I do think that the *Kehl* case 08:52:09 that I handed up to you is relevant and, Your Honor, I have another case that I would like to hand up called *Henrikson versus Strapon*, and that cite is 314 -- excuse me. 758 Northwest 2d 205, and that's a 2008 case from the Court of Appeals in Wisconsin. I've got a copy for the Court and copy 08:52:36 for plaintiffs' counsel.

08:52:42 And, Your Honor, this is kind of a second case that addressed this issue of punitive damages in the context where you've got a hit and run and the issue as to whether or not the run part of that, fleeing the scene, should come into
08:52:55 evidence for punitive damages.

And of course Your Honor said you read the *Kehl* case, and there the Court held that that was not connected to the actual injury because there was no evidence that fleeing the scene, as reprehensible as that conduct is, caused an
08:53:12 injury to the plaintiff in that case, and the evidence should not have come in, according to the court, for punitive damages purposes.

And this was a very similar case with a drunk driver who also fled the scene. And, Your Honor, I think that the
08:53:27 language that is germane here is the court was describing the issue in *Kehl* and the court held that as far as the issue as it was framed there in that case, in this 2008 case, whether the conduct may be a basis for an award of punitive damages when it is related to the transaction underlying a
08:53:50 plaintiff's recovery for compensatory damages but does not cause injury or contribute to loss.

I think that is exactly the scenario we have here, that the aggressive marketing that plaintiffs want to introduce is not evidence that directly attributes to the
08:54:10 loss based on the design defect claim.

08:54:13 And, obviously, evidence of what was provided to doctors, as we've all discussed, is relevant. But the underlying motive is not.

And as your court held -- the Court held in the 08:54:25 summary judgment motion, or the order, document that's Docket 12007, the reason why we don't have a failure-to-warn claim in this case is because the Court held "Because plaintiffs present no evidence that Mrs. Hyde or Dr. Henry would have acted differently in the face of different 08:54:45 warnings by Bard, summary judgment is warranted on the failure-to-warn claims.

So, Your Honor, I submit that this evidence about conduct and motivation for marketing is precisely going to the issue of failure to warn and we will be in this situation 08:55:04 where we run the risk that the jury will award punitive damages to the plaintiff based on a claim that's not in the case. And we'd also run into, obviously there, some due process concerns.

And the last thing I will point out is, and this is 08:55:20 what is just kind of bollixes me about this issue, is I could perhaps understand the plaintiffs' position if they were claiming in this case that the Eclipse filter was not a defective filter and that it would have somehow spared the plaintiff of the injury that she experienced. But the 08:55:40 Meridian filter was not on the market at the time of the

plaintiffs' filter implantation.

And so the two things that we have at issue here are the G2X and the Eclipse and the plaintiffs have presented a lot of evidence in this case those are the same filter, same issues with defect, same risk of fracture, and that the electropolishing of the Eclipse filter didn't do anything to alleviate potential fracture.

So from a causal connection of how any sort of aggressive marketing could have somehow led to the injury that we have here, Your Honor, I just submit that that's just a causal connection that is not present.

THE COURT: For purposes of punitive damages.

MR. ROGERS: Yes, Your Honor.

THE COURT: All right. I understand that position.

Okay. I want to read this document over that Mr. Lopez has provided. We'll look at the case that you cited.

I think there are two issues I have to decide. One is whether this is admissible for purposes of punitive damages, which does bear on the two cases that have been cited, but the other is whether it's admissible for purposes of proving design defect.

I want to think about those two issues. So I will do that and get you a decision.

MR. ROGERS: May I -- Your Honor, I need to hand the

08:56:57 case up.

THE COURT: Okay.

Anything else we need to address before we get the jury in?

08:57:06 MR. ROGERS: Your Honor, one last thing that's very brief and I just want to flag for the Court a concern that occurred during Mr. Baird's testimony yesterday.

Obviously, Mr. Baird was asked "You have not thought about IVC filters since you left the company" on the

08:57:22 examination that Ms. Helm did, and when Mr. O'Connor came back he asked about testimony. He never said a question that said "trial" or anything like that, but, you know, we made it through one pass at that and the witness made it through without referring to prior trial, but second pass through,

08:57:39 the witness did say "I had no need to until these trials," plural. I don't know if any of the jurors picked up on that or not, but did he say plural.

And so, Your Honor, I do have a concern that if witnesses are going to be asked about testimony, that we be

08:57:59 mindful that when pressed long enough these witnesses are going to say something. And I think we just need to be very careful about that so that the defendant is not prejudiced.

And, Your Honor, that kind of ties in with a -- there is a current news article, granted it is in Atlanta.

08:58:20 It's not an article, it's actually on the internet from a

station, channel 11 in Atlanta, which is a story about the Booker trial. And of course references the verdict from the Booker trial. That is out there. It just hit the internet this weekend and is available if one is searching around on the internet about IVC filter trials.

So that exacerbates my concern about trying to stay on these witnesses long enough until perhaps they may reference a trial.

THE COURT: Well, you're not suggesting that the wording be any different than what Mr. O'Connor was doing, are you? I mean he was careful to say "in prior testimony."

MR. ROGERS: Mr. O'Connor's question, he never said anything that I felt like was inappropriate.

THE COURT: Okay. Well, I think it is an issue we need to be sensitive to. I didn't see a problem with the way the questions were phrased. And I'm not sure it will come up again with another witness. And I think the jury's been repeatedly admonished about not doing their own research. I'll continue to do that at appropriate times.

Okay. Let's bring the jury in.

(The jury entered the courtroom at 9:00 a.m.)

THE COURT: Thank you. Please be seated.

Morning, ladies and gentlemen.

JURORS: Morning.

THE COURT: Counsel, as the jury was coming in they

09:01:03 mentioned to Nancy and Traci that when a video is playing, the folks who are listening on the headsets can't hear it on the headsets because it's not in the court's sound system. So what they've been able to hear has been a little faint.

09:01:18 So if you pull a mic down by one of the speakers, that will put it into the sound system and through their headsets.

You can still use that, but I think the point is we want it to be picked up by the headsets and so we need a mic

09:01:31 by one of the speakers.

Hopefully that will do the trick.

MR. LOPEZ: Let us know if it's too loud.

THE COURT: Ladies and gentlemen, we'll continue with the deposition testimony of Dr. Henry where we left off

09:01:47 last evening.

Plaintiffs' counsel, you may proceed.

(Video testimony of Dr. David Henry resumed.)

THE COURT: Hold on just a minute.

(Jurors with headsets do thumbs-up gesture.)

09:02:11 MR. O'CONNOR: We're good.

MR. LOPEZ: At this time we should go back to the beginning of the question.

THE COURT: That's fine.

We're just going to go back to the beginning of that

09:02:26 question, ladies and gentlemen.

09:02:27 (Video testimony of Dr. David Henry played.)

MR. LOPEZ: That concludes that testimony.

At this time plaintiffs are calling Mr. John Van Vleet.

09:16:53 THE COURTROOM DEPUTY: Sir, if you'll please come forward.

JOHN VAN VLEET,

called as a witness herein, after having been first duly sworn or affirmed, was examined and testified as follows:

09:17:43 MR. LOPEZ: May I proceed, Your Honor?

THE COURT: You may.

D I R E C T E X A M I N A T I O N

BY MR. LOPEZ:

Q Good morning.

09:17:49 A Good morning.

Q Mr. Van Vleet, tell the jury who you are where you work, what your position is, please.

A Sure. I am vice president of clinical and regulatory affairs for Corindus Vascular Robotics based in Waltham,

09:18:03 Massachusetts.

Q And at one point in your career did you work for Bard Peripheral Vascular --

A I did.

Q -- here in Tempe?

09:18:12 A Sure. I worked for Bard Peripheral Vascular from

09:18:15 June 2007 to December of 2017.

Q And what was your position when you left Bard?

A Vice president regulatory and clinical affairs.

Q Are you a medical doctor?

09:18:31 A No.

Q What is your educational background?

A I have a bachelor of science in biology with a minor in chemistry from Purdue. I'm a licensed medical technologist, and I have an MBA.

09:18:45 Q Have you ever worked for what's called a CRO?

A Not technically. I have an LLC and I've worked independently in 2003 and I currently have an LLC and I work some sideline work independently. That would be kind of like a contract research organization.

09:19:05 Q I was going to ask. You and I knew what that meant. CRO is a contract research organization?

A Yes.

Q That's an organization that gets involved in clinical trials; right?

09:19:14 A Correct.

Q It's independently hired by a company to oversee and maybe design a clinical trial?

A Usually they're hired to do the data collection and the monitoring for a company. Mostly it's execution or

09:19:30 operational work.

09:19:31 Q And when you were at Bard, were you involved in any testing that was done where you had to engage a CRO?
A So when I joined Bard they had a couple different contract research organizations that they were working with on several
09:19:47 different trials.
Q Okay. I'm going to try to make -- I'm trying to ask simple questions because of the time issues. I know you have some yourself. I just wanted to know whether or not while you were at Bard, did you have any interaction with the CRO?
09:20:00 A Yes.
Q Okay. And what is an IRB?
A It's called an institutional review board. It's a hospital or institution-based committee that is an ethics committee that makes decision on whether or not a study can be
09:20:14 conducted.
Q All right. And don't they monitor the study as well in case there's any potential problems with the clinical trial subjects in the event they might want to stop the trial?
A Correct. They have to make an annual recertification
09:20:28 decision.
Q And when did you start with Bard again? Was it June 2007?
A June of 2007; correct.
Q By June of 2007, the G2 device had been on the market for almost two years; right?
09:20:44 A It was on the market. I can't recall exactly how long,

09:20:46 but, yes, it had been on the market when I joined.
Q When you joined Bard in 2007, there had already been a clinical trial for retrievability that had taken place; true?
A Correct. Yes.
09:21:04 Q So you came on to that clinical trial -- well, why don't you tell the jury, how was it that you got involved in the EVEREST trial?
A When I joined Bard, the EVEREST trial had completed enrollment and follow up and was in the final phases of having
09:21:20 the clinical study report being written.
Q Okay.
So you didn't have -- you weren't involved in the actual trial itself adjudicating adverse events, interacting with the CRO, interacting with the actual investigators; true?
09:21:37 A Not during the study, but toward the end of the study in the writing up of the clinical study report I was involved in those discussions.
Q Now, prior to your joining Bard, you had a long history of having worked for other medical device companies; correct?
09:21:53 A Yes.
Q And what were those companies?
A I started with Zimmer, which at that point was part of Bristol-Myers Squibb. I worked for DePuy for six years prior to the Johnson & Johnson acquisition and then six years
09:22:06 afterwards. And then I was independent for a while and then

worked for Smith & Nephew and through a start-up company.
Q What did you do with those firms?
A Started working first doing preclinical work, which was basic design of animal studies, and then moved into human clinical work, which was the clinical research side of it. And then probably maybe 15 years into it, also took on regulatory affairs responsibilities.
Q Now, when you joined Bard and you were assigned whatever tasks you were assigned to with respect to the EVEREST trial, by then how many clinical trials had you been involved in regarding Class II device that had gone through the 510(k) process like the EVEREST trial?
A I believe only one other study for a Class II device. Actually, no. Two.
Q When you came on and -- was one of your first assignments to deal with the EVEREST trial and help prepare the final report?
A Yes.
Q Was there already a team in place when you got there?
A Yes.
Q And did that team include medical doctors?
A Yes. At least one. Correct.
Q Was that Dr. Lehmann?
A No. Dr.-- I'm not sure if Dr. Lehmann is a medical doctor, but, yes, he was involved in the study; correct.

09:23:33 Q And Dr. Ciavarella was involved?
A Yes.
Q You interacted with both of those individuals?
A I interacted -- yes. Mostly with Dr. Ciavarella.
09:23:42 Q So you don't know whether Dr. Lehmann was a medical doctor or not?
A Honestly, I don't. I think he's a Ph.D as well, but he could be a medical doctor. I never actually met him in person.
09:23:52 Q Are you familiar that Dr. Lehmann had actually had other positions at Bard before you got there?
A I'm not really sure. I knew he was an acquaintance or friend of Dr. Ciavarella's and they worked together.
Q When you got there, as you were getting educated on the
09:24:07 G2, did people at Bard provide you with the clinical history of that device?
A Yes.
Q Okay. And what did they provide to you?
A Mostly surrounding the protocol for the study and just any
09:24:23 information about the enrollment and followup.
Q Okay. And the other jobs that you mentioned, did you have any involvement with the Smith & Nephew knees that were manufactured by one of those companies?
A I did, but as a consultant not actually as an employee.
09:24:46 Q And how did you consult on those products?

09:24:50 A I was part of a investigation in the field involving evaluation of early implants of a knee system.
Q Did you support the safety and effectiveness of those devices?
09:25:04 A Indirectly.
Q And what happened to those devices?
MR. ROGERS: Objection, Your Honor. Relevance.
THE COURT: Hold on.
What's the objection?
09:25:14 MR. ROGERS: Objection is relevance, Your Honor.
THE COURT: Sustained.
THE WITNESS: I --
THE COURT: Sir, sustained.
BY MR. LOPEZ:
09:25:21 Q Did there come a time when your support of the safety and effectiveness of another medical device that involved knees came into question?
MR. ROGERS: Objection, Your Honor. Same objection.
THE COURT: I don't understand the relevancy. Do we
09:25:35 need to talk about this, Mr. Lopez?
MR. LOPEZ: That's all right, Your Honor, I can move on.
THE COURT: Okay.
BY MR. LOPEZ:
09:25:41 Q Did you also work with the Smith & Nephew hips?

09:25:48 A I did not work with Smith & Nephew hips.
Q Did you work with any of the DePuy hips?
A Yes.
Q How about the Johnson & Johnson talcum powder --
09:26:02 A No.
Q -- you work with that?
MR. ROGERS: Objection, Your Honor. Relevance.
THE COURT: Sustained.
BY MR. LOPEZ:
09:26:09 Q And Zimmer hip and knee devices, did you work with those?
A I worked with both with Zimmer.
Q Except for the talcum powder, are the rest all 510(k) products?
A One of Zimmer products was actually one of the first PMA
09:26:28 hips ever, and the knee systems, I believe, were 510(k).
Q Okay. So I think you've described in prior testimony that your involvement in the EVEREST trial was to help prepare the clinical data for submission to FDA. Do you remember that?
A Yes.
09:26:48 Q And that's still true today; right?
A Yes.
Q And you also had the responsibility to review and approve any documentation or any reporting that goes to FDA; correct?
A Yes.
09:27:03 Q Now, let me -- you did not sign the truth and accuracy

09:27:06 statement, however, that was submitted to FDA; correct?
A No. The actual correspondent that would have prepared the submission to the FDA would have signed that.
Q Explain to the jury how that works. The person that signs
09:27:17 it is relying on information that's being provided to him or her by other people that are working on the submission; true?
A True.
Q And the person that probably had more information about that because that was the person who reviewed and approved the
09:27:36 documentation would have been John Van Vleet. Would you agree with that?
A I would have had probably at least as much information about the clinical study report. The test -- bench testing. I'm probably not the top most knowledgeable person. The
09:27:52 quality person signs that portion of the submission to the FDA.
Q Well, is it fair to say that the person who signs -- who would have signed the truth in accuracy statement submitted to FDA in this case, in the case of the EVEREST study, would have
09:28:08 depended quite heavily on the input of Mr. John Van Vleet?
A It's actually the way other way around. They would have depended on the input of the team and then I would review the entire document and vouch for the truth and accuracy of the document. Even though I didn't sign it, internally I would
09:28:26 have signed it.

09:28:28 Q He or she would have had some interaction with you and would have said Mr. Van Vleet, are you good with this report, can I sign the truth and accuracy statement?

A So normally in the process that person would have signed

09:28:38 the truth and accuracy statement and then presented it to me and I would do a final review and report and audit of the document.

Q So you would bless it, basically.

A Yes.

09:28:49 Q So what was the purpose of the EVEREST study?

A So the purpose of the EVEREST study was to demonstrate the safety and effectiveness of the retrievability of the G2 IVC filter system.

Q It was not designed to look at the long-term safety and

09:29:04 effectiveness of the device; right?

A It was simply designed to evaluate the safety of the retrievability and then a month after. It lasted until 30 days after retrieval.

Q But the despite the fact -- well, when it was being

09:29:22 submitted, therefore, to FDA for its scrutiny, it was being submitted to FDA to determine whether the FDA was going to allow Bard to add the option of retrievability to an already permanent device that was on the market, the G2; correct?

A Correct.

09:29:42 Q Now, describe Dr. John Lehmann's role in preparing the

reports of the results of the EVEREST study.
A I believe he was -- might have been a statistician or at least a reviewer and contributor to the report.
Q Now, wasn't Dr. Lehmann originally going to be the person who signed Bard's submission to the FDA reporting on the EVEREST study?
A I believe he signed it, but actually procedurally that would not have been necessarily the way the SOP's would have called for it to be.
MR. LOPEZ: Could we, Felice, call up 1036.
BY MR. LOPEZ:
Q Do you have that in front of you Mr.-- can you see that okay?
A Yes.
Q That's an e-mail from you on September 27, 2007; correct?
A Yes.
Q And this is in reference to the EVEREST trial?
A Yes.
Q And you've been there about two months; right?
A Yeah. Yes.
Q Trial already done; correct?
A Yes.
MR. LOPEZ: And, Your Honor, I'd like to offer 1036 in evidence at this time.
MR. ROGERS: No objection, Your Honor.

09:31:00 THE COURT: Admitted.

(Exhibit 1036 admitted.)

BY MR. LOPEZ:

Q Below that is an earlier e-mail dated September 27, but it's earlier in the day. Do you see that, sir, at the bottom?

09:31:08 A I did earlier, yes.

MR. LOPEZ: Can we go to page 2 of this exhibit, Felice, and look at the top. And could you -- just the top part there. Perfect.

09:31:22 BY MR. LOPEZ:

Q And, sir, this is you writing to the team; correct?

MR. LOPEZ: May I publish to the jury, Your Honor?

THE COURT: You may.

THE WITNESS: Yes.

09:31:39 BY MR. LOPEZ:

Q And you wrote to the team that "You'll notice quite a bit of concern regarding the re-addition of the retroperitoneal bleed which, as you know, this group decided some time ago to remove."

09:31:52 Did I read that correctly?

A Yes.

Q And you also state at the bottom, "At this point, I feel that we have reached an impasse as to how to proceed. I believe this now has become a business decision."

09:32:07 What was a business decision?

09:32:10 A The editorial changes of the clinical study report.
Q And what's the significance of retroperitoneal bleed that might happen in a clinical trial in a patient who has an IVC filter?
09:32:24 A I don't recall this in particular, but a peritoneal bleed is basically a bleed into the abdominal cavity.
Q Well, what can happen if the device perforates and someone's on anticoagulation, they could actually bleed into what's called the retro -- the peritoneal cavity; correct?
09:32:42 A That can happen.
Q And that type of event can actually cascade into other more serious events that could actually cause the patient to die.
A Correct.
09:32:54 Q And here you're saying that with respect to that finding, the group had decided to remove that from the report; right?
A It was never removed from the report. It was removed from a classification section where the complications are listed. But all of those are included and go to the FDA.
09:33:10 Q It was down-classified; right?
A Reclassified.
Q Did -- was that red flagged so whoever was going to review this several-hundred page submission to the FDA would actually look at that to see whether they placed any significance to
09:33:25 it?

09:33:26 A So FDA would have already seen this because this goes -- these complications go to the FDA throughout the life of the study every six months.

MR. LOPEZ: Move to strike. Nonresponsive, Your
09:33:35 Honor.

THE COURT: Overruled.

BY MR. LOPEZ:

Q Sir, I asked you whether or not it was red flagged so that in this document that was being sent to FDA, the FDA could
09:33:43 look at that and say we had a retroperitoneal bleed in this, I want to question that. Was that red flagged?

A I wouldn't agree with that.

Q Okay. Let's look at the first page of this Exhibit 1036, please. The very first paragraph. And this is you writing to
09:34:07 Mr. DeFord. Who is Mr. DeFord?

A He was the chief scientific officer and head of clinical affairs at Bard corporate.

Q And, sir -- and you're writing this e-mail; correct?

A Yes. I believe so, yes.

09:34:24 Q Let's look at the section -- well, let's read the paragraph. It states, "In the interest of being discriminating and picking our battles, we compromise and got alignment around" -- what's that, revision G?

A Yes.

09:34:42 Q "In which, I might add, much of rhetorical distractions

09:34:47 from revision D, original Lehmann version."

What's "original Lehmann version" mean?

A A version of the clinical study report that was provided to us by John Lehmann.

09:34:57 Q And that was added back in by David and John Lehmann? David, meaning Dr. Ciavarella?

A Dr. Ciavarella.

Q And then it reads, "In the interest of progress and conciliation, we swallowed it, against our better judgments

09:35:10 and moved ahead. Do you see that?

A Yes.

Q "Furthermore, Micaela -- Michelle Micaela signed off and David signed off. Then last weekend after you and David discussed the proper role of consultants and that John Lehmann

09:35:24 would no longer be used."

Did I read that correctly?

A Yes.

Q What happened is Dr. Lehmann was dismissed from this project; correct?

09:35:33 A I -- he -- I'm assuming he was. He did not report to me and I'm really not sure what his actual role was.

Q Well, in fact he was the only outside MD consultant that was involved in the preparation of this report; isn't that true?

09:35:50 A Again, I don't know that he's an MD. But he certainly was

09:35:53 involved in the preparation of the report.

MR. LOPEZ: Can we go down to the very next paragraph, Felice. That first sentence.

BY MR. LOPEZ:

09:36:02 Q And you wrote, "I respectfully request that the authorship of this paper be assigned -- reassigned from John Lehmann to John Riviere and we move ahead."

Did I read that correctly?

A Yes.

09:36:16 Q Who is John Riviere?

A Director of clinical research at Bard Peripheral Vascular at the division in Tempe.

Q Is he an MD?

A No.

09:36:26 Q Is he a ph.D?

A No.

Q Does he have any clinical experience at all with respect to utilization of IVC filters?

A No. He's not a medical practitioner.

09:36:35 Q What's his background?

A He's a molecular biologist.

Q Is he a doctor who has ever been trained in statistical analysis?

A He's had training in statistical analysis but he's not a

09:36:51 doctor.

09:36:52 Q So you don't know whether Dr. Lehmann was an MD or Ph.D but he could have been both; right?
A He could have been both; correct.
Q And whoever he was, the decision was made that that person
09:37:03 would not be involved in the authorship of the final report but somebody who was a microbiologist would be doing that. Correct?
A Correct.
Q Actually -- yes. All right.
09:37:25 Doctor -- one of the things Dr. Lehmann wanted to do that went against the grain with respect to why he was dismissed is he did not want you to include the SIR guidelines because they are not intended for anyone except physicians and are not for manufacturers' use; isn't that true?
09:37:43 A I'm not sure why he did not want to include them but, yes, I do know that he did not want to the include the SIR guidelines.
Q Sir, you remember your testimony in the Booker trial -- I'm sorry. In the Booker -- in another case?
09:38:07 A In particular? Yes, I do remember testifying in another case.
MR. LOPEZ: And can we call up 4547, page 54.
And show that to Mr. Van Vleet, please.
MR. O'CONNOR: She's working on it.
09:39:29 MR. LOPEZ: 4547.

09:39:31 4547. Page 54.

BY MR. LOPEZ:

Q Sir, I'll direct your attention to this testimony.

By the way, were you under oath when you gave this

09:40:00 testimony?

A Yes.

Q And you were asked, "You were aware that Dr. Lehmann did in fact object to putting the SIR guidelines in the final report?"

09:40:10 And your answer was, "I'm sure that when I reviewed the documentation I would have seen that."

Was that your testimony?

A Yes.

Q And then on page 55, the very next page, which is page -- you see where we are at line 8 through line 18?

09:40:24 A Yes.

Q You were asked, "Based on your understanding of the guidelines, they were not intended for manufacturers; true?"

"Answer: I don't think they were intended for

09:40:39 anybody but perhaps the clinician."

"Was that your answer, sir, at your deposition?"

And you agreed, it was.

Then below --

THE COURT: You need to ask a question, Mr. Lopez.

09:40:52 BY MR. LOPEZ:

Q That's what you testified to, sir?

A Yes.

Q Now, these guidelines that Dr. Lehmann was objecting to,
09:41:07 do they have anything to do with whether or not there were complications in the EVEREST trial that were, in fact, relating to some design issues with the device?

In other words, do the SIR guidelines talk about complications as a result of a company's design issues or
09:41:36 design defects in their products?

A No. I believe they were just a general guideline to clinicians as to things that could be expected to happen after placement of IVC filters.

Q Do the SIR guidelines even address the issue of caudal
09:41:55 migration and rate of caudal migration?

A They have a migration estimate of percentage of cases of migration in general. They don't specify whether it is caudal or any direction, it's just movement.

Q My question is specifically -- as you know -- let me ask
09:42:16 this: As you know, the unique design problem that the G2 filter had was it was -- it had a significant number of migrations of the device moving downward; correct?

MR. ROGERS: Objection, Your Honor. Argumentative.

THE COURT: Overruled.

09:42:35 THE WITNESS: There were cases within the EVEREST

09:42:37 study that did migrate. But it was a relatively small number of cases.

BY MR. LOPEZ:

Q We'll get to that in a second. But there was a unique
09:42:47 design feature about the G2 that actually the company acknowledged before you got there; correct?

A I don't --

MR. ROGERS: Objection, Your Honor. Foundation.

THE WITNESS: I don't know. I mean, I don't know
09:42:59 what happened before --

THE COURT: He said he doesn't know.

BY MR. LOPEZ:

Q There was a unique issue with the clinical performance of the G2 from the EVEREST study where it had a large percent,
09:43:13 over ten percent of the devices, that actually moved downward over two centimeters; correct?

A I believe it was over ten percent; correct.

Q And there were actually 30 or 40 percent of those that actually moved downward but had not reached two centimeters;
09:43:32 correct?

A Yes. All of the movements were reported in the clinical study.

Q I understand. But there was acknowledged from the EVEREST study that one of the unique problems that this device had was
09:43:44 it was not staying where the doctors were putting it in this

09:43:46 small trial and that almost half of them were moving downward and 12.1 -- 12 percent of them were moving downward almost an inch or more; correct?

A Over two centimeters; correct.

09:44:02 Q All right. And my question to you, sir, is where in the SIR article that you were talking about here is that phenomenon discussed?

A They're -- in the categorization of the different clinical events that can happen after placement of a filter, there was

09:44:22 a listing of migration, and I believe the SIR guidelines and their survey of the studies that had been done published that somewhere between 2 and 15 percent, or maybe it was 20 percent, but between 2 and 15 percent was a range one could expect to see after placement of any IVC filter.

09:44:41 Q It doesn't say that in those guidelines, does it? It doesn't say that's the expectations that doctors have for migration when they place an IVC filter anywhere in that article, does it?

A I -- I can't say exactly how it's stated. It's a survey

09:44:58 of all published reports on filters.

Q No. We've got to be really careful with words here, sir. When you say something says that doctors are supposed to expect something, we're going to -- the jury's going to believe that. So I want to know whether or not the SIR

09:45:15 guidelines actually state that these are what physicians

09:45:19 should expect happen with IVC filters that they're putting in their patients.

MR. ROGERS: Objection, Your Honor. Argumentative and compound.

09:45:28 THE COURT: Sustained.

MR. LOPEZ: Your Honor --

BY MR. LOPEZ:

Q Sir, do the SIR guidelines give -- stand for the proposition that whatever rates or whatever is being reported

09:45:41 in the medical literature are what people and doctors should expect should happen when an IVC filter is implanted in them? Does it say that?

A I don't have the article in front of me, but essentially what it says --

09:45:57 Q Sir, if you don't know --

MR. ROGERS: Objection, Your Honor.

THE COURT: Mr. Lopez --

Hold on.

Mr. Lopez, let him finish the answer.

09:46:03 THE WITNESS: So at the time it was published and then it was later republished with more information, it was taking all of the available published reports on studies of filters, a survey, and it was looking at the different phenomenon they were discussing, migration included, and they

09:46:21 were saying across all of these studies this is the range of

09:46:24 that event that has been found. It's kind of like a meta-analysis of all of the studies.

BY MR. LOPEZ:

Q So you didn't mean to say these were expected

09:46:34 complications in those ranges on devices that Bard was selling; true?

A I'd say it was a survey of published information.

Q And nowhere does the SIR guidelines that you've been talking about -- that you've been talking about here use the

09:46:51 word that these are acceptable complications, does it?

A I don't -- I don't believe so. I'm not sure.

Q Now, do these guidelines excuse Bard from its requirement to maintain as safe and effective a device as it can and to test it in the manner in which it should be tested and design

09:47:21 it to make it as safe as possible?

A I don't think they have anything to do with that. I think Bard has a responsibility to the FDA and to the patients to maintain appropriate safety standards.

Q Do they -- do the guidelines excuse Bard from their

09:47:36 requirement to be as safe and effective as a predicate device?

A Again, I don't think the guidelines have anything to do with Bard's responsibility.

Q And the guidelines don't deal with whether or not, from a regulatory standpoint, Bard or any other IVC manufacturer may

09:47:56 be selling a device that is either adulterated or misbranded

09:47:59 or being illegally marketed; true?
A Don't have anything to do with that.
Q Nor do the guidelines deal with whether a company should legally or ethically stop selling an IVC filter if a company
09:48:12 determines that the filter poses an unreasonable or unacceptable risk of serious injury to patients as determined by the company's own internal risk analysis; true?
MR. ROGERS: Objection, Your Honor. Argumentative.
THE COURT: Overruled.
09:48:26 THE WITNESS: The article has nothing to do with that.
BY MR. LOPEZ:
Q And nor do the guidelines condone the acceptance of increased risks when those risks can be significantly
09:48:36 decreased or eliminated with safer alternative designs; true?
A The article has nothing to do with any of those things.
Q And the authors of the IVC -- of these guidelines do not condone making an IVC filter less safe as a permanent device if the retrievable device obtains 510(k) clearance -- I'm
09:48:59 sorry. Let me start that over.
The guidelines do not condone making an IVC filter less safe as a permanent filter if it later gets permission from FDA to market it as both a retrievable and a filter -- and a permanent filter; true?
09:49:19 A So neither the authors nor the article has anything to do

09:49:24 at all with that.
Q Do the IVC -- do these guidelines even address the risk of a metal strut migrating to a patient's heart and lungs?
A I do not believe -- I don't it have in front of me. I
09:49:39 would have to look at it.
Q Might those have been some of the reasons why Dr. Lehmann didn't want you to use the SIR guidelines to do any comparisons to your clinical findings in the EVEREST trial?
A I really don't know why Dr. Lehmann objected, so I can't
09:49:59 speculate on that.
Q I thought you were the one overseeing this whole process of putting the report together.
A Yes.
THE COURT: Hold on a minute, Mr. Lopez.
09:50:08 MR. ROGERS: I'm sorry to interrupt, Your Honor. It appears one of the jurors is having an issue with his hearing device.
MR. LOPEZ: Oh. I'm sorry.
JUROR: I'm sorry. It keeps dying on me.
09:50:16 THE COURT: Counsel, let's have you approach for a minute while we're taking care of that.
(Bench conference as follows:)
MR. ROGERS: Sorry. He's been trying to get the attention of Traci.
09:50:42 THE COURT: Mr. Lopez, 45 minutes after we talked

09:50:48 about not mentioning other trials and I admonish you to be careful and 43 minutes after defense counsel noted that there is an article in the paper today about the Booker trial, you mention the Booker trial. I have a great deal of difficulty
09:51:04 believing that that was inadvertent.

Would you please explain yourself.

MR. LOPEZ: I'm just going to tell you, I'm looking at an outline and it says Booker trial right there in my outline and for me to go to that transcript.

09:51:17 And I assure you 100 percent on my brother's soul that that was completely inadvertent. It was only because it was in my outline. I would never do something like that, Your Honor. I would never do it. I promise you.

THE COURT: You heard the discussion 45 minutes
09:51:35 earlier.

MR. LOPEZ: Of course I did, Judge. I mean, I just got caught up in the moment. I was looking at my notes and I was reading my next segue and it was -- it says Booker trial -- I'll show you my notes. It says Booker trial
09:51:47 testimony. Right there. So I'm going down the list and not thinking --

THE COURT: A little more quiet.

MR. LOPEZ: I'm not thinking, I'm reading. As soon as I said it I knew I said the wrong thing.

09:51:58 I mean this is -- I mean -- let's just deal with

09:52:03 that part of it. I promise you. I'll show you my notes.

THE COURT: Were you going to say anything?

MR. ROGERS: No, Your Honor. It's just an issue for which I really have no remedy. I mean, I think if there was

09:52:14 an instruction to the jury, the cure is worse than the disease. And the only thing we could potentially do is move for mistrial, which I don't think --

MR. LOPEZ: Do what?

MR. ROGERS: Move for mistrial.

09:52:26 And, Your Honor, I don't want to lose this jury. I don't want to waste all the resources of the court restarting this case by moving for mistrial. But if this happens again, I don't think we'll have any other option but to do that.

THE COURT: All right.

09:52:41 I accept your representation, Mr. Lopez, but we need to be very careful on this point because there's an article out today on this very subject. It would be very prejudicial if somebody went to look up the Booker trial after having heard that reference.

09:52:56 MR. LOPEZ: The other thing, Your Honor, I must say this is the first time I've ever been restricted from doing that in a case where there have been other -- as you've got to put in context to the fact he was just in a trial not that long --

09:53:05 THE COURT: Well, that's not an excuse.

09:53:07 MR. LOPEZ: I understand. I know it's not.
THE COURT: We've done this in all of the trials.
MR. LOPEZ: We have. Right.
THE COURT: Okay.
09:53:13 (Bench conference concludes.)
THE COURT: Thank you, ladies and gentlemen.
Is the headpiece working?
JUROR: Yes. All right.
THE COURT: Don't hesitate to raise your hand if
09:53:41 those batteries die again.
JUROR: I will.
MR. LOPEZ: May I proceed?
THE COURT: You may.
MR. LOPEZ: Thank you.
09:53:49 BY MR. LOPEZ:
Q Sir, going back to the EVEREST final report, there were discussions among your colleagues at Bard to change the definition of "migration" that was going to be put in the final report; true?
09:54:03 A There was a discussion with FDA about the migration limits; correct.
Q And had you and your colleagues been successful in changing that definition, it would have eliminated three patients from being counted as a migration; true?
09:54:22 A No. Actually, the definition that we had proposed was the

09:54:26 one that was defined in the SIR article and that's what FDA agreed to.

Q Now, later on in the trial we'll hear about a document called a guidance document. You're familiar with that, the

09:55:07 510(k) guidance document as relates to IVC filters?

A Yes.

Q And in that guidance document, the FDA recommends that five millimeter migrations be included as migrations; true?

A I'd have to go back. I'm not exactly sure.

09:55:33 Q How many fractures were in the EVEREST study?

A I believe there was one fracture.

MR. LOPEZ: Can we see trial Exhibit 4617, please, page 65.

This is -- may I move --

09:56:15 BY MR. LOPEZ:

Q This is the final report, sir, of the EVEREST study. Do you want to see the first page of the document?

MR. LOPEZ: Why don't we show him page 1 of the document, Felice.

09:56:34 4617. There we go.

BY MR. LOPEZ:

Q Do you see that?

A Yes.

Q Okay. And then on page 58 -- I'm sorry.

09:56:46 MR. LOPEZ: Page 65 of the exhibit but page 58 of

09:56:48 the report, and the last -- the second to last -- in the middle paragraph, Felice, where it says "filter fracture." In the box. I'm sorry, in the box. Right there.

BY MR. LOPEZ:

09:57:17 Q So in the EVEREST study, a filter fracture --

THE COURT: Mr. Lopez, this exhibit is not in evidence.

MR. LOPEZ: Oh. May I move 4617 in evidence.

MR. ROGERS: No objection.

09:57:29 MR. LOPEZ: May I publish?

THE COURT: 4617 is admitted.

(Exhibit 4617 admitted.)

MR. LOPEZ: May I publish, Your Honor?

THE COURT: You may.

09:57:38 BY MR. LOPEZ:

Q Do you have that in front of you, sir?

A Yes.

Q We just talked about filter fracture in the EVEREST study; right?

09:57:44 A Correct.

Q Filter fracture was found on pre-retrieval image at 92 days. Do you see that?

A I do.

Q So we have in the first three months, in this particular

09:57:51 patient, a filter fracture; correct?

09:57:54 A Correct.
Q "Fluoroscopy revealed mild filter tilt with a fractured strut external to the IVC."
What does that mean?
09:58:04 A The fractured strut, which is the little tiny foot on it, was seen penetrating the IVC.
Q "One fractured filter arm and one fractured leg were noted in the extravascular space."
Did I read that correctly?
09:58:20 A You did.
Q So there were actually two fractures in this study; right?
A It appears there were, yes.
Q And there were fracture of not just an arm, but of a leg. Correct?
09:58:30 A Correct.
Q And retrieval in this particular patient was unsuccessful despite extensive effort because the apex of the filter appeared to be embedded in the IVC wall and could not be engaged by the Recovery Cone. Correct?
09:58:46 A Correct.
Q Is that important clinical safety information?
A Yes.
Q And is that important clinical safety information that you believe that both patients and physicians might want to know
09:58:58 about this filter as having occurred in a controlled clinical

09:59:02 trial?
A Yes.
Q So your answer should have been two fractures, right, not one.
09:59:15 A A fracture of one or more filter elements was observed in one case, and I think that language is also in the instructions for use.
Q Are you familiar with the Asch pilot study, the retrievability study?
09:59:31 A Yes. Vaguely.
Q Sounds very similar to what Dr. Asch experienced in a short-term study; true?
A I don't remember that detail about it.
Q And getting back to the EVEREST study, three of the 61
09:59:46 attempted retrievals were unsuccessful because the filter was so embedded in the side of the wall the filter couldn't be removed; right?
MR. ROGERS: Objection, Your Honor. Foundation.
THE COURT: Hold on just a minute.
09:59:58 Overruled.
THE WITNESS: Can you repeat the question, please.
BY MR. LOPEZ:
Q Three of the 61 attempted retrievals were unsuccessful because the filter had become so embedded in the side of the
10:00:11 wall of the vena cava because of its tilting it could not be

removed; true?
A I believe so.
Q And then there were 39 -- by the way, there were 100 patients originally enrolled in the EVEREST study?
A Yes.
Q And 39 of those were not even selected for retrieval; correct?
A Within the period of the study; correct.
Q And were any of these patients followed beyond six months?
A Not in the protocol for the study. Six months or one month post retrieval I think is the way the protocol was written.
Q So the best data that this study was designed to provide was whether or not within six months this device could be safely removed enough so that you'd get clearance from FDA to add that to your indications; true?
A Yeah, to evaluate the retrieval and through six months, basically.
Q And you told FDA that based on the data that you have here, that this device could be safely removed within six months; right?
A That we presented the data from the clinical trial and requested clearance for retrievability.
Q In fact, the mean time period was some time period less than six months; right?

10:01:31 A That by definition would have to be, yes.
Q And once these patients that were out of the study who were not retrieved, they were then just sent out to their open medical care and treatment by their physicians?
10:01:49 A They were medically managed by their primary physicians; correct. Presumably.
Q So whatever happened to those 39 patients after they were released from this study, Bard didn't follow; true?
A Not under a clinical trial.
10:02:03 Q This study could have been designed that way; right? Could have followed patients longer than six months.
A Presumably it could have.
Q And by then, Bard had a pretty good track record of how this device was performing in the open marketplace; true?
10:02:19 A We certainly monitor the performance of the device through complaints and reports.
Q While this study was going on, Bard was doing internal risk analysis of the G2 filter based on the information they were collecting in the open patient population because there
10:02:36 was not a controlled clinical trial going on; true?
A We have to do that for every device that we manufacture, yes. Correct.
Q It was starting to learn things about the design and safety of that device that it did not know before it launched
10:02:51 it; true?

10:02:53 A Yep. Absolutely. With every complaint that's reported on every device we go back and evaluate it against the design of the device.

Q It was tracking and trending its performance against other 10:03:05 devices on the market; right?

A That's usually what the quality group does. I'm not the expert in that field, but, yeah.

Q And it was determining whether or not the way it was performing was actually performing in a manner in which they 10:03:18 were expecting it to perform; true?

A Yes. That's part of the quality system regulations.

Q And they were tracking and trending this device to see if it was actually performing the way they were representing it to doctors and patients that it would be -- that it would 10:03:32 perform; true?

A Again, that's a quality function but that's part of the quality system regulations, yeah.

Q And they were performing -- well, let me ask you this: Did anyone at Bard tell you they had already done an internal 10:03:47 risk analysis on caudal migration based on the data they were getting in from the patient population and had determined that it had an unacceptable risk of the serious injury --

A I'm not --

Q -- to patients from just that data they were collecting in 10:04:06 the first four, five months it was on the market?

10:04:08 A I'm not familiar with that at all.
Q Did it -- did Bard advise you when you were preparing this report and about to communicate with the FDA that they had done -- actually done a comparison between the Recovery filter
10:04:24 which was taken -- as you know, taken off the market for patient safety reasons; correct? You knew that.
A I -- I wasn't working at Bard at that time.
Q I understand you weren't. But my question to you is you knew the Recovery filter -- Bard stopped selling the Recovery
10:04:41 filter because of significant safety -- patient safety issues; true?
A I don't know that to be true.
Q Okay.
Well, do you know -- did they tell you as you were
10:04:51 getting ready to prepare this report and give a truth and accuracy statement to FDA that they had actually done comparisons to both the Simon Nitinol filter and the Recovery filter with respect to its complications and its risks to patients?
10:05:08 A That wasn't part of my review of the clinical study report at all and I -- frankly, I don't know if I looked up any data around that.
Q Did Bard share with you information -- well, let me ask you some fundamental background questions first.
10:05:28 This study also had a medical monitor; correct?

10:05:30 A Yes.
Q And that medical monitor was an independent person by the name of Dr. Chris Kandarpa?
A Kandarpa; correct.
10:05:41 Q Did you ever have any interaction with Dr. Kandarpa?
A I did not directly.
Q And he was the person -- he was the doctor that was assigned by Bard through their CRO to adjud- -- what we call adjudicate all of the adverse events that were happening in
10:05:58 the study; right?
A Correct.
Q Did anyone give you access to Dr. Kandarpa when you were getting ready to prepare your final report?
A I would have had access to him. I certainly saw his
10:06:10 review of the study and the review of the complaints that were reported, or adverse events.
Q Did you -- so Dr. Kandarpa was a physician; right?
A Yes.
Q Do you know anything about his background?
10:06:25 A He's an interventional radiologist. Boston based. That's about as far as I know.
Q In fact, he knew Dr. DeFord well; right?
A Yes. Dr. DeFord knows him; correct.
Q And he was selected because of his credentials and because
10:06:41 of his writings and because of his teachings and because of

his background with respect to IVC filters; true?
A Presumably. That would be how I would select him, but he was selected by the CRO.
Q Because of his experience and all those wonderful things why you would want to hire someone like that to pay close attention to what was happening with the patients in the study; correct?
A That would be how I would do it. I'm not sure what the criteria they used was.
Q Did anyone ever share with you the meeting minutes where Dr. Kandarpa is quoted with respect to what's going on in that study?
A I didn't see any meeting minutes in preparation of this report.
Q Did you -- when you said you had access to Dr. Kandarpa, did you actually talk to him?
A I did not.
Q Did you have him assist you in preparing the final report?
A He assisted indirectly because he was part of the committee or the group that would review all adverse events; correct.
Q But he didn't get to review the final report; right?
A No. No. He did not.
Q Did Dr.-- well, these meeting minutes, they were available to you if you wanted to see them; right?

10:07:58 A We actually didn't have those in house. So they presumably could have been, I just didn't know about them. Those were closed meetings and so the sponsor, by their policy, was not allowed to participate in them.

10:08:15 Q Were you advised at any time before preparing the final report that Dr. Kandarpa's impression as he was adjudicating these patients that were in the clinical trial, that there were simply too many complications from this device?

MR. ROGERS: Objection, Your Honor. Hearsay.

10:08:32 THE COURT: Sustained.

MR. LOPEZ: May we approach on that one, Your Honor?

THE COURT: Sure.

If you want to stand up, ladies and gentlemen, feel free.

10:08:48 (Bench conference as follows:)

MR. LOPEZ: The testimony's coming. You approved this part of Dr. Kandarpa's deposition.

THE COURT: That question was still calling for hearsay.

10:09:06 MR. LOPEZ: Whether or not he was aware of --

THE COURT: You said was he advised. In other words, did somebody tell you.

MR. LOPEZ: I gotcha.

THE COURT: So that clearly called for hearsay

10:09:13 statement.

10:09:14 MR. LOPEZ: Okay.

(Bench conference concludes.)

THE COURT: Thank you.

MR. LOPEZ: Thank you, Your Honor.

10:09:27 BY MR. LOPEZ:

Q Sir, were you advised Dr. Kandarpa was of the opinion there were too many complications in that study?

MR. ROGERS: Objection, Your Honor. Hearsay.

THE COURT: Sustained.

10:09:40 BY MR. LOPEZ:

Q Were you advised -- were you aware of any opinion by anybody that there were too many complications in that study?

A No.

Q Were you aware from anybody that there was an opinion that

10:10:03 there were too many tilts from that study?

MR. ROGERS: Objection, Your Honor. Hearsay.

THE COURT: Overruled.

THE WITNESS: No.

BY MR. LOPEZ:

10:10:14 Q If in fact Dr. Kandarpa was of the opinion that the Bard filter should be redesigned based on his observations, was that something you shared with FDA?

A I don't know that that was -- I never heard that. Would have shared it with the FDA had that been brought to our

10:10:38 attention.

10:10:41 Q Do you know if Dr. Kandarpa had the authority to stop the study?
A I -- so he's the clinical events committee. He could have made a recommendation. Normally there's a group called a data
10:10:57 safety monitoring board, and that study in particular didn't have one, and that would be the group that actually would have authority to terminate a clinical trial.
Q Do you know what Dr. Kandarpa's feelings were about whether or not the study should be stopped?
10:11:14 A No.
Q And if you didn't know, you would not have been able to share that with FDA when you submitted this study; right?
A We would have shared everything we knew at the time.
Q When the study was going on, wasn't Bard already
10:11:36 reconsidering the design of the G2 filter?
A I -- I don't recall. May have. But I wasn't -- I wasn't part of that.
Q Well, did the clinical trial subjects know that before they enrolled in the study that the medical director,
10:11:59 Dr. Ciavarella, who we've talked about earlier, thought that people ought to be using the Simon Nitinol filter because it had less complications than the G2?
MR. ROGERS: Objection, Your Honor. Hearsay.
THE COURT: Hold on just a minute.
10:12:20 Overruled.

10:12:30 THE WITNESS: I don't know what Dr. Ciavarella thought and didn't know any of that.

BY MR. LOPEZ:

Q Well, my question to you was not whether you knew what he
10:12:37 thought or not. Do you know if the clinical trial subjects were provided with that information: By the way, our medical director thinks we have a device that's safer than this and anyone who would want to choose this device ought to choose our safer alternative device.

10:12:54 A I don't -- I didn't know that at the time and so I don't know whether or not patients should know. They're completely two different filter designs.

Q The G2?

A And the Simon Nitinol. Correct.

10:13:08 Q Well, 39 of those patients had the device remain in them beyond six months; right?

A Yes.

Q As a matter of fact, the protocol for the study was that after six months, these would actually convert to permanent
10:13:20 devices. Do you remember that?

A They could be left in for permanent or they could be retrieved at whatever time a physician felt.

Q Well, let's talk about that.

You represent -- the company represents that the G2,
10:13:33 G2X, and Eclipse filters can be retrieved safely at any time

10:13:37 during the life of the patient; true?
A Yes.
Q And the only clinical data that you had on that was the EVEREST trial; right?
10:13:44 A Yes.
Q And the EVEREST trial only established that 58 out of 61 could that happen; true?
A Correct.
Q And that there were three within six months that couldn't
10:13:58 be removed because the device had tilted and embedded so much they could not be removed percutaneously from the patients' vena cava; right?
A That's the results of the clinical trial; correct.
Q In view of that, Bard continued to market the G2, G2X, and
10:14:15 Eclipse filter with unlimited time of safe retrievability; true?
A There was no specification as to a limit on when the device could be retrieved.
Q And that was Bard's IFU, correct?
10:14:27 A That was the IFU that was written together with the FDA.
MR. LOPEZ: Move to strike, Your Honor. Nonresponsive. Assumes facts not in evidence. Lacks of foundation.
THE COURT: Overruled.

BY MR. LOPEZ:

Q That IFU belongs to Bard; right?

A The IFU is a co-authored document with the FDA.

Q Sir, who is the expert in the mark- -- in the design, manufacturing, testing, marketing, research of IVC filters, Bard or FDA?

A It would be the sponsor or Bard.

Q Okay. And no one at FDA -- let me ask you this: The IFU that you're talking about, who at FDA were these discussions had with?

A The primary reviewer, the director of the division, and the medical reviewer.

Q Were you there?

A Yeah. For many of them, yes.

Q None of those people that ever designed, marketed, and implanted, extracted, had anything to do with IVC filters other than what Bard was providing to them in this submission; true?

A I don't know what their personal expertise would have been, but Bard was the designer, manufacturer, tester, of the filter; correct.

Q But ultimately, the decision as to what you were going to put in the IFU and in marketing materials, that final decision was Bard's; correct?

A Absolutely not. That's always the FDA's final decision.

10:16:00 Q Sir?
A Beg your pardon?
Q You're saying it's the FDA's final decision as to what's in an IFU?
10:16:09 A Yes.
Q So you allowed folks who had no clinical history, no knowledge of internal communications about risk, no knowledge about internal testing, no knowledge about practicing medicine with these devices determine what doctors should say -- what
10:16:31 doctors should know about these devices in an IFU?
MR. ROGERS: Objection, Your Honor.
BY MR. LOPEZ:
Q Is that true or not?
THE COURT: Hold on.
10:16:37 What's the objection?
MR. ROGERS: Objection is, Your Honor, foundation and it's a compound question.
THE COURT: Overruled.
THE WITNESS: Could you restate the question?
10:16:46 BY MR. LOPEZ:
Q I won't put us through that one more time. Other than to say that the IFU is Bard's IFU; whatever's in it, Bard's responsible for what's in it, not FDA, not anybody else; true?
A It's a legal document that is, at the end of the day,
10:17:03 co-authored and approved and posted by FDA.

10:17:09 Q And if it doesn't say what it's supposed to say and if it doesn't give doctors and patients information they should have, that's Bard's 100 percent responsibility; true?
A It is not. The medical reviewer at FDA goes through that. 10:17:23 And I would have to disagree with your characterization of the medical reviewer. That was a position very experienced in dealing with this type of patient population. Practicing physician.
Q Are you telling us you're kind of running away a little 10:17:38 bit from what's in the IFU and that we --
A Not at all.
Q -- ought to be looking at someone else who's responsible for that?
A Not at all. We provide everything we know about the 10:17:46 device to the FDA and collaboratively with them author the final version of the IFU.
Q Who is Chris Ganser?
A He is -- was a corporate officer responsible for quality at Bard corporate.
10:18:06 Q A step or two, maybe, above your position?
A Yes, absolutely.
Q So if Dr. Ganser was going to testify in this case that irrespective of anything that happens at FDA, Bard is 100 percent responsible for the safety and effectiveness of 10:18:18 their device and how they -- what they put in the IFU and how

10:18:22 they market it, you're disagreeing with Mr. Ganser?
A I have to disagree with him just categorically based on the way the FDA operates.
Q But the bottom line, however this comes out with this
10:18:40 discussion, that whatever FDA when you're having these discussions with them about the things you just talked about, they're relying on Bard to provide them with truthful, accurate, and complete information and not leave out any material information for them to consider. True?
10:18:56 A Absolutely.
Q And the FDA can only do its job if in fact Bard is doing that; right?
A Correct.
Q Let's change gears here for one second.
10:19:57 Now, during your tenure at Bard, there was an article that was published that caused quite a stir at Bard, the Nicholson study. Do you recall that?
A I do.
Q And that study or article raised a number of concerns
10:20:14 about a number of Recovery and G2 filter fractures, and included with that were the number of fractures that were actually not staying near the filter but actually embolizing in people's hearts and other parts of the body; true?
A Yes.
10:20:39 MR. LOPEZ: Would you put up 587, please.

BY MR. LOPEZ:

Q Sir, do you see 587? Is that the article we're talking about?

A Yes.

Q And this is published in the Archives of Internal Medicine?

A Yes.

Q And this article is an article that's in a journal that is an authoritative journal?

A I'm not an expert in the field of internal medicine. I can't comment on whether or not it's authoritative. But it is a peer reviewed journal.

Q And it's in a journal -- irrespective what journal it's in, it's about Bard devices and would have been an article Bard would have been required to have read and taken into consideration; right?

A Yes.

Q And this was published when?

If you look at the bottom --

A August of 2010.

Q Okay. And what is the title of this article?

A Prevalence of Fracture and Fragment Embolization of Bard Retrievable Vena Cava Filters and Clinical Implications Including Cardiac Perforation and Tamponade.

Q And were you still with Bard at the time?

10:22:17 A Yes.
Q Still had responsibilities for the G2 filter?
A Yes.
Q G2X filter?
10:22:21 A Yes.
Q And the approaching Eclipse filter; right?
A Yeah, I think that's the right time period.
Q And what is the conclusion reached by Dr. Nicholson on that -- in this article?
10:22:42 MR. ROGERS: Objection. Hearsay.
MR. LOPEZ: Not offering it for the truth, Your Honor. It's a learned treatise.
THE COURT: Under 803(18)?
MR. LOPEZ: Yes, sir.
10:22:53 THE COURT: Objection is sustained.
Criteria for 803(18) has not been satisfied.
BY MR. LOPEZ:
Q Is this an article that you reviewed and relied upon?
A This is an article I certainly reviewed.
10:23:06 Q And one that you responded to? You were involved with the response to this article; true?
A Yes.
MR. LOPEZ: At this time, Your Honor, I'm not offering it for the truth of the matter asserted but for
10:23:18 Bard's and Mr. Van Vleet's reaction and responses. The

effect this article had on him and the company and for notice.

MR. ROGERS: Same objection, Your Honor.

THE COURT: I take it with that statement you want him to state what's in the article?

MR. LOPEZ: Pardon me?

THE COURT: You want him to state what's in the article as opposed to describe his reaction, is that what you're saying?

MR. LOPEZ: Well, both.

THE COURT: Objection is sustained as to stating what's in the article. It's hearsay.

You can certainly ask him about his reaction and the company's.

BY MR. LOPEZ:

Q Before the Nicholson article, which was in 2010, Bard was already aware that its G2 and G2X and Eclipse filters had experienced a significant number of not just fractures but fractures that were embolizing into people's hearts and lungs; true?

A So I'm not going to say what "significant" means, but we certainly collected adverse events and medical device reports and reported them to the FDA and all those were definitely investigated.

Q What was it about the Nicholson study that was so

upsetting to you and others at Bard?

A It was an extreme outlier in terms of any clinical performance that we had seen either in studies that we had conducted or other studies that had been published.

Q What do you mean studies you conducted? The study you conducted was the EVEREST study.

A EVEREST study. Correct.

Q You knew about a fracture in 61 patients that occurred 192 days, I think, after implantation of an arm and a leg; right?

A In 83 patients.

Q Well, you didn't follow all 83 of those patients beyond a certain time period; right?

A No, I'm just specifying the denominator was based on the images that were available, which was 83.

Q One of the concerns at Bard was lost filter sales as a result of this study; true?

A I'm sure that was probably a concern of sales force; correct.

Q Let me ask you, when you got the Nicholson study, did you hire any doctors to look at the internal data that you had at Bard to see whether or not what Nicholson was reporting was actually consistent with Bard -- with what Bard knew all along?

A We certainly discussed -- I don't know if we hired physicians, but we certainly discussed it with people that we

had worked with as principal investigators for the study or people that were very familiar with filter practice. And we -- we did a lot of asking.

Q My question was a little different than that.

My question was did you hire anybody, independent person, to come in and look at all of the complaint data that you had gathered over the previous five years to see if maybe Dr. Nicholson found something that we've known all along and looked at the complaint files to see if whether or not there were similar types of events that -- at a rate that was unexpected, unintended, and significantly higher than maybe what had been reported with the Simon Nitinol filter or other filters on the market? Just that question. If you can answer.

A Absolutely. We hired a physician in particular that consulted a lot on filters as we discussed this with FDA and had him look at all of our information and be available to FDA as well.

Q Okay. Again, I want to make sure we're on the same page here.

Bard has a lot -- they're required to maintain complaint files; right, with all of the details of the complaint files.

A Yes.

Q Correct?

10:27:40 A Correct.
Q And they're required to track and trend those complaints to see whether or not this is leading to something where they may have to make some changes to the design, to the warnings,
10:27:49 and do something to protect people from maybe this recurring in the future; true? That's their duty.
A Correct.
Q That's not FDA's duty, that's your duty; right?
A Correct.
10:27:59 Q My question was did you have someone, a statistician, a biostatistician, Dr. Lehmann, anyone like that come from the outside and look at all of the that data and say, you know what, what Dr. Nicholson is reporting we -- people have been reporting to us for the last five years. Did anyone do that?
10:28:21 A So we have internal statisticians. I'm not sure if the quality organization hired anybody outside, but we definitely had outside physicians reviewing this information.
Q Did somebody look at all that data going back five years, look at the same data that was reported in Dr. Nicholson's
10:28:38 study and provide you a report to see if there were any statistically significant increased risks of those kinds of events that were happening all along before Dr. Nicholson published his report?
A So we evaluated our historical data and knew that the
10:28:54 rates that Dr. Nicholson was reporting was completely outside

10:29:00 of anything that we had seen. It was not representative of our experience.

Q I didn't ask -- again, I'm not asking you that. I'm asking you whether or not someone came in and looked at the 10:29:10 adverse event data and looked at all that and did a statistical analysis comparing that same data to other devices on the market. Did that happen?

A I -- I'm not sure. But it's very likely it would have because the quality organization continuously monitors the 10:29:29 trends and --

Q And there should be --

THE COURT: Excuse me, Mr. Lopez.

We're going to take a break at this time, ladies and gentlemen. We'll plan to resume at 10:45. Please remember 10:29:38 not to discuss the case or do any research. We'll see you in 15 minutes.

(Recess taken from 10:30 recess to 10:45. Proceedings resumed in open court with the jury present.)

THE COURT: Thank you.

10:45:45 Please be seated.

You may continue, Mr. Lopez.

MR. LOPEZ: Thank you, Your Honor.

BY MR. LOPEZ:

Q Mr. Van Vleet, the concern about this article that's 10:45:54 written by Dr. Nicholson and others was that it talked about a

10:45:58 prevalence of fractures in two Bard devices, right, the G2 and Recovery?

A It -- it -- sorry. The concern with the article or my concern personally?

10:46:12 Q Well, I mean the concern that Bard had was that it was like just singling out Bard and the prevalence of fractures from Bard, two of Bard products; true?

A The concern was the rate, which was something Bard had never seen before.

10:46:29 Q Okay.

MR. LOPEZ: Now, can we look at 1621.

Can you show that to Mr. Van Vleet.

Felice, 1621, please.

BY MR. LOPEZ:

10:47:08 Q Sir, are you familiar with that document?

A I'd have to look at it here.

Yes. I -- I think I've seen it before.

Q Right. This was prepared for in reaction or response to, what, an online presentation by Dr. Nicholson entitled

10:47:41 Fractures of the Nitinol IVC Filter?

A Yeah. There was a cath conference from Washington Hospital through an organization called CRT. It's kind of like a live grand rounds with different presentations, and that's when we first became aware of Dr. Nicholson's study.

10:48:03 Q In fact, you became aware of it before it was published;

10:48:06 right?
A Yes.
MR. LOPEZ: I'd like to move 1621 in evidence.
MR. ROGERS: No objection.
10:48:10 THE COURT: Admitted.
(Exhibit 1621 admitted.)
MR. LOPEZ: Could we publish just the top part of that to the jury, Your Honor. May I publish to the jury?
THE COURT: You may.
10:48:24 MR. LOPEZ: Just the top part of that, Felice.
BY MR. LOPEZ:
Q So this was an online presentation -- what's CRT?
A Cardiovascular research -- gosh. It's a scientific organization that is based in Washington and holds an annual
10:48:48 meeting.
Q And would it be fair to say that CRT thought that the information that was being reported by Dr. Nicholson was important enough that it be provided to the medical community even before the publication?
10:49:07 A Yeah, I --
MR. ROGERS: Objection. Foundation.
THE COURT: Sustained.
BY MR. LOPEZ:
Q Do you know why it is CRT would have done an online
10:49:15 presentation of this before it was published?

10:49:17 A I don't.

MR. LOPEZ: Okay. Could we look at 1821, please.

BY MR. LOPEZ:

Q And, sir, do you see that this is an e-mail that -- a

10:49:36 chain where you were included? Do you see there in the middle?

A Yes.

Q And you were very much involved in the discussions that were taking place regarding the Nicholson article; true?

10:49:50 A Yes.

MR. LOPEZ: Your Honor, I'd like to offer 1821 into evidence.

MR. ROGERS: No objection.

THE COURT: Admitted.

10:49:55 (Exhibit 1821 admitted.)

MR. LOPEZ: May I display, Your Honor?

THE COURT: You may.

MR. LOPEZ: Felice, if you can show the first paragraph as well as the recipients, all the names on the

10:50:09 e-mail.

BY MR. LOPEZ:

Q So this was -- you have that in front of you, sir?

A Yes.

Q You see you're on the e-mail; right?

10:50:18 A Yes.

10:50:18 Q And who is Bret Baird?
A He was the marketing manager for IVC filters at that time.
Q And Bill Little?
A Vice president of marketing.
10:50:28 Q And then you're there and a number of other folks from, what, a variety of departments, would you say?
A Quality, R&D. Correct.
Q And Rob Carr's on there as well; right?
A Yes.
10:50:40 Q And so this was -- this article kind of brought in everybody; right? Different departments?
A Yes.
Q And this was being brought to your attention and the others by a sales representative?
10:50:56 A Yes.
Q And he wrote to you: "Bill, John, and Gin, I want to bring to your attention a presentation that is live on" -- it's that website -- "regarding Bard filter features."
Do you see that? Did I read that correctly?
10:51:16 A "Fractures." Yes.
Q And "Dr. W. Jay Nicholson presented a number of peers on November 4 through a recorded Webex session regarding his recent study on fractures in his facility."
Did I read that correctly?
10:51:31 A Yes.

10:51:31 Q And who is Preston Whelan?
A I believe he was a territory manager for Bard.
Q "One of our Bard TMs called yesterday and then today with the details regarding this. His facility has just stopped
10:51:48 using G2 because of this presentation."
Did I read that correctly?
A Yes.
Q And there was concern about the fact that if this problem that was being discussed by Dr. Nicholson on this website was
10:52:06 actually a problem with the G2 filter, that other doctors might stop using the G2 at this time; right?
A It could have been, yeah. I don't know.
Q Now, yesterday we talked about there was some discussion about the baggage of the G2 and was part of that baggage the
10:52:28 fact that Dr. Nicholson was -- had written this article and it was showing the first article of somebody who was doing retrospective review of some of the hospital's patients and found what they thought was a prevalence of G2 and Recovery fractures?
10:52:46 MR. ROGERS: Objection, foundation.
THE COURT: Sustained.
BY MR. LOPEZ:
Q Are you aware of the this discussion about G2 baggage?
A I'm not.
10:53:00 MR. LOPEZ: And then, Felice, if we can go down to

10:53:02 the very last paragraph of this first page.
BY MR. LOPEZ:
Q "Brian" -- do you have that now in front of you, sir?
A I do.
10:53:13 Q "Brian and I spoke briefly about this and the York facility has reported to us some fractures. I have appointed Preston to our filterfacts.com website and G2 articles."
Did I read that correctly?
A Yes.
10:53:29 Q "At this point he is trying to protect the rest of his business."
Did I read that correctly?
A Yes.
Q So filterfacts.com was a Bard website; right?
10:53:39 A Yes.
Q So there were some -- so Bard wanted to make sure they had information out there on their own website.
A Our responsibility's to always provide a fair and balanced source of information for physicians and patients.
10:54:00 Q Okay. And ultimately, a team was put together because you wanted to -- you wanted to go and find out what Dr. Nicholson had really done here and you wanted to investigate further; true?
A Absolutely. We had to collect all information on any Bard
10:54:26 product complaints.

10:54:28 Q Let me ask you: Before Dr. Nicholson on his own decided to look retrospectively at some of the patient populations at this hospital, had Bard ever gone around the country or the world and said, you know, we're getting certain reports about
10:54:43 certain complications we're having with our device, we'd like to pay for you to look at some of your medical records going back two, three, four, five years and see if you can see a pattern or some prevalence of those complications, you know, in this hospital. Did Bard ever do that?
10:55:05 A So not necessarily pay somebody to do it, but supported the work of retrospective reviews. I personally was involved at Massachusetts General in a retrospective review. By this time at least three dozen articles had been published on a variety of filters out there and they included a lot of
10:55:24 retrospective reviews.
Q Okay. But I mean something like this where they actually go to a hospital or somewhere in a hospital and look back at specifically how Bard filters were performing in that hospital over a period of four, five years.
10:55:39 This is the first time that's ever happened; right?
Well, let me withdraw the question.
Bard never sponsored such a survey or retrospective study; true?
A Not directly sponsored, but certainly supported.
10:55:53 Q Okay. Did Bard ever sponsor what's called a registry of

10:56:00 these devices when it was first put on the market so they could follow how patients were doing on their devices if they were left in long term?

A No.

10:56:09 Q Did they ever do a survey of doctors to determine how their patients were doing after having a device in them for a number of years?

A Not directly. But we supported a system to track patients and follow them.

10:56:27 Q That happened after -- that didn't happen until after the Nicholson article; right?

A That had actually been -- that happened simultaneously because it had actually been contracted with McKesson prior to the article.

10:56:47 Q Now, sir, isn't it true that the Nicholson article was also discussed in multiple congressional hearings?

A I have no idea.

Q You know that -- were you involved in some of the legal goings on regarding the Nicholson article?

10:57:06 MR. ROGERS: Objection, Your Honor. Vague.

MR. LOPEZ: Okay, it was vague. It was, Your Honor I'll rephrase it.

BY MR. LOPEZ:

Q Are you aware that Dr. Nicholson was actually threatened

10:57:18 with legal action regarding his article by Bard?

10:57:22 A I'm not familiar with that.

MR. ROGERS: Objection, Your Honor.

May we approach briefly?

THE COURT: Yes, you may approach.

10:57:29 Feel free to stand up, ladies and gentlemen.

(Bench conference as follows:)

MR. ROGERS: Yes. Your Honor, I think where this is going is Mr. Lopez is trying to lead up to an introduction of a letter from one of my law partners to Dr. Nicholson. I may

10:57:51 be wrong about that. If that's where we're headed, I think that is highly prejudicial under 403 and also not relevant under 401. I wanted to go ahead and get that out there.

MR. LOPEZ: They produced this, by the way.

THE COURT: You do want to use this?

10:58:08 MR. LOPEZ: Yes. I don't have to put in the whole article. They're asking -- here's a lawyer asking him to retract the article. I need to get into the fact that Bard asked them to retract this article.

THE COURT: Why is that relevant?

10:58:22 MR. LOPEZ: Because they're going to attack the article as being an article that has no scientific basis, had flaws. Dr. Feigal did it last time and a number of witnesses did that, and the truth is that nobody -- Bard did not hire research people or peer reviewers to look at the article,

10:58:42 they hired lawyers.

10:58:59 Can I add one thing? Put it this way: They didn't go after the SIR. It has more flaws than this. The SIR is their friend. They don't attack articles like that. Their go-to is to attack an article that is not their friend.

10:59:16 And I'm about to show some other evidence to this witness that will show this article is something that didn't -- shouldn't ever have been written. They knew about all this before.

THE COURT: What article shouldn't have been

10:59:28 written?

MR. LOPEZ: The Nicholson article.

THE COURT: You say Nicholson article shouldn't have been written?

MR. LOPEZ: No, no. Shouldn't have gotten to that

10:59:37 point is what I'm saying. In other words, this device had all these problems. Dr. Nicholson shouldn't have been the first person to tell the medical community about the prevalence of these issues.

THE COURT: We're getting very far afield. The

10:59:46 objection --

Hold on, Mr. O'Connor.

The objection is to the relevancy of the defense firm in this courtroom having written a letter to Dr. Nicholson on behalf of Bard.

11:00:02 You've, as much as you can with this witness because

11:00:05 he can't authenticate the Nicholson article, brought out the fact that it was out there, what Bard's doing in response. You clearly asserted in this Nicholson article as having put Bard on notice of having serious problems with the filter.

11:00:24 That's all in front of the jury.

I'm having trouble with the 403 objection to pointing out that the very lawyers sitting in this courtroom defending Bard wrote a letter to Nicholson saying your article's inaccurate, you should retract it.

11:00:37 MR. LOPEZ: First of all, I wouldn't do that without knowing that is potential recusal issue for them. I was just going to say has a lawyer written -- were lawyers hired and did they send a letter threatening that he needed to retract his article. That's all. And see if this refreshes his

11:00:55 recollection.

THE COURT: Well, what I -- I still think it's pretty far afield. What I'm going to do is sustain the objection at this point.

If you feel, after cross-examination, that they

11:01:07 impugned the Nicholson article to an extent that it makes this more relevant, then you can call a sidebar and I won't charge you a bean for it.

MR. LOPEZ: Fair enough.

THE COURT: Because I think at this point it is --

11:01:19 it's far afield from what you've been covering and what I

11:01:23 think is the relevancy of the Nicholson article.

MR. LOPEZ: That's fair.

(Bench conference concludes.)

THE COURT: Thanks, ladies and gentlemen.

11:01:43 Go ahead.

BY MR. LOPEZ:

Q Sir, are you aware of any intimidation that may have taken place that was directed to Dr. Nicholson after he wrote his article?

11:01:52 A No.

Q In fact, one of the doctors, Dr. Agarwal, I think, was one of the doctors whose records were reviewed. Do you know Dr. Agarwal?

A I don't.

11:02:13 MR. LOPEZ: I'm going to backtrack for just one second and let's look at 2252, please.

Can we go to -- may I display, Your Honor? This has already been admitted into evidence.

THE COURT: What's the number?

11:02:40 MR. LOPEZ: 2252.

THE COURT: Let's just confirm we have it in evidence.

THE COURTROOM DEPUTY: I don't show it in evidence.

MR. LOPEZ: Maybe not. There's another version of

11:02:47 this that doesn't have quite as much.

BY MR. LOPEZ:

Q Sir, can you take a look at 2252.

A Yes.

Q I think we saw a part of this e-mail string earlier. Do you recall that?

A I'm not sure we saw this one, but I have seen it before.

Q And I think if you look there on the first page you're involved in the string?

A Correct.

MR. LOPEZ: Your Honor, at this time I would like to offer 2252 in evidence.

MR. ROGERS: No objection.

THE COURT: Admitted.

(Exhibit 2252 admitted.)

MR. LOPEZ: May I publish?

THE COURT: You may.

BY MR. LOPEZ:

Q Why don't we start from -- let's look at page 3 first.

And before -- you acknowledged this is an e-mail on page -- starting page 2 from John Lehmann to you and others --

A Yes.

Q -- on September 25, 2007. Okay.

And if you go to page 3, you look at section -- almost at the middle of the page where it says regarding --

MR. LOPEZ: Just do that whole paragraph, Felice,

please.

There you go. Perfect.

BY MR. LOPEZ:

Q This is one of the issues that we talked about earlier that Dr. Lehmann was expressing. It should not include validation and documentation regarding SIR categorization of events; true?

A I'm not sure that I can take that from what that says. It just says validation and documentation.

Q Let's go down to the next paragraph, A.

The first -- in the middle there where it reads David -- there it is. See where it says "David and Michelle"?

A Yes.

Q "I infer from my conversation with David and Michelle that this effort may have been done by BPV staff without review by the Medical Monitor."

Did I read that correctly?

A You did.

Q "And in a manner not consistent with the FSRs."

What are FSRs?

A I'm not sure.

FSR. Final study report. Yeah.

Q These were concerns being sent to you by Dr. Lehmann; right?

A Yes.

11:05:24 Q And we've already established that this Medical Monitor was Dr. Chris Kandarpa.
A Yes.
Q So if we see in a document "Medical Monitor" in capital
11:05:36 letters like that, we're talking about the same doctor, Kandarpa; right?
A I would assume that would be Dr. Kandarpa.
Q And then the next sentences in that paragraph reads: "In my opinion, if we don't have documents supporting this data
11:05:52 analysis as comparable to the rest of the FSR data, then we can't properly include it in the FSR without clearly distinguishing it from the fully validated data."
That was Dr. Lehmann's recommendation?
A That's what he wrote here; correct.
11:06:14 Q Did you follow that advice?
A The report was fully reviewed by everybody involved in the process.
Q Did you follow Dr. Lehmann's advice?
A I can only assume we did. Those reports are audited by
11:06:26 multiple external people.
Q Let me ask you, how soon after September 25 when Dr. -- Dr.-- I'm sorry. After -- yeah. After September 25 when Dr. Lehmann wrote this e-mail to you and Mr. Riviere and Dr. Ciavarella and Michelle Micaela was he fired?
11:06:44 A I don't believe he was ever fired.

11:06:46 Q He was let go from the study.
A I don't know the timeline.
Q Okay. Let's look at the next page. Page 4 of the exhibit Page 4 of the exhibit. Section 5. Under Conclusion.
11:07:07 This is Dr. Lehmann again writing with respect to the discussion and conclusion section of what was being submitted with the report; right?
A It's part of his e-mail; correct.
Q And this was going to be Bard's truthful and accurate
11:07:23 representation of what they were submitting as the conclusion, the take-away message of that study; true?
A The truthful statement applies to everything included in the entire regulatory filing, so by definition yes.
Q And Dr. Lehmann wrote, "I realize that we have an
11:07:45 unsupported regulatory statement that needs modification relating to the EVEREST trial demonstrating substantial equivalence to similar devices, which it obviously didn't do."
Did I read that correctly?
A You did.
11:07:58 Q "So I've deleted the sentence 'The general performance of the Recovery G2 filter system and safety profile are consistent with similarly marketed devices' in the second to last paragraph and revised the conclusion text in both Section 10 and similarly at the end of the synopsis."
11:08:19 Correct?

11:08:20 A Correct.
Q Dr. Lehmann did that.
A That's what it states here.
Q But what happened is after Dr. Lehmann left, that language
11:08:27 is actually included in the discussions and conclusions; true?
A There numerous modifications from this revision to the final one that went to the FDA.
Q But all we have to do is look at that to determine whether or not what Dr. Lehmann was saying was actually followed;
11:08:41 correct?
A I'm sorry, say that again.
Q We just have to look at the Conclusion section that is being discussed here to see whether or not Bard actually took what Dr. Lehmann advised and followed that advice; right?
11:09:05 A Yes.
Q Okay.
MR. LOPEZ: Let's look at 4617 please.
And let's go to page 84.
And this is -- I think I moved this. This is in
11:09:50 evidence, Your Honor. May I display it to the jury?
THE COURTROOM DEPUTY: 4617's in.
THE COURT: Yes, you may.
MR. LOPEZ: Page 84 of the exhibit number which is page 77 of the document, please.
11:10:05 And could you highlight the "Overall Study Results"

paragraph.

BY MR. LOPEZ:

Q Sir, take a look at it. That's almost precisely what Dr. Lehmann told you you shouldn't do; right?

A Correct.

Q Was that your final decision to bless that language in this document?

A It would have been since I ultimately sign off on it; correct.

Q Okay.

MR. LOPEZ: And let's go to the first page of this document, and could we just look at the date where it says Initial Enrollment right about the middle of the document.

And then could you grab all those dates that are with that, please.

BY MR. LOPEZ:

Q Okay. You see the initial enrollment was December of 2005?

A Yes.

Q And then the final enrollment July 24, 2006. Do you see that?

A Yes.

Q Now, were you aware that same December of 2005, Dr. Ciavarella and others were concerned about a design feature of the G2 filter that caused it to migrate downward?

11:11:33 A No, I was not aware of that.

Q Do you know if any of the trial subjects were or Dr. Kandarpa or anyone else, any investigators were aware of that?

11:11:42 A Not -- not to my knowledge.

MR. LOPEZ: Can we have 709, please.

BY MR. LOPEZ:

Q Sir, you're familiar with this document?

A Yes.

11:12:06 Q I think you authored it; right?

A I helped to write it; correct.

Q And this was August 10th, 2014.

A Yes.

Q And what was the purpose of this document?

11:12:22 A It was to propose to the FDA that Simon Nitinol filter -- I'd have to go back through it. But there's a multi-company study that the FDA was participating in and they are evaluating -- and it's ongoing right now, it's called Preserve. They're evaluating all currently marketed IVC

11:12:47 filters in a multicenter study.

The Simon Nitinol has a very few number of users and it would be difficult to include them in the study because it would delay enrollment for the rest of them. I think that's the purpose of that is to provide an option to give them the

11:13:07 information they needed.

11:13:09 Q Isn't it true that because Bard --

MR. LOPEZ: Your Honor, I'd like to move to admit 709 at this time.

MR. ROGERS: No objection, Your Honor.

11:13:18 THE COURT: Admitted.

(Exhibit 709 admitted.)

BY MR. LOPEZ:

Q Sir, isn't it true that because Bard decided not to participate -- include the SNF device in the Preserve study

11:13:30 that they chose to -- the option of just removing it from the US market?

A Yeah. We asked to have it included and the overall committee felt the slow rate of enrollment would hold up the entire study so they declined to have us participate.

11:13:49 Q And that was, what, about latter part of 2015, 2016?

A I don't recall exactly when but, yeah, subsequent to that we decided to discontinue it.

MR. LOPEZ: I'd like to publish Exhibit 709, please, Your Honor, to the jury.

11:14:06 THE COURT: You may.

BY MR. LOPEZ:

Q So I'm not going to walk you through the entire document. You're trying to convince the FDA that SNF really does not need to be involved in the Preserve study; right?

11:14:23 A Correct.

11:14:23 Q If we look at page 6 of this document, it includes your language to FDA about one of the reasons why it does not need to be in the Preserve study; correct?

A Yes.

11:14:41 MR. LOPEZ: Could we go to that last paragraph.

Is there any way you can highlight that part where it says -- where it begins "Again, the first SNF" and all the way down to basically the bottom.

FELICE: Where?

11:15:09 MR. LOPEZ: About four lines down -- there you go. And -- there you go. Perfect. Okay.

BY MR. LOPEZ:

Q And you wrote this in August of 2014; true?

A Correct.

11:15:20 Q "The first SNF 510(k) was cleared April 20th, 1990," and it gives -- that's the 510(k) number?

A Yes.

Q "And has been on the US market for over 24 years as a permanent inferior vena cava filter option."

11:15:38 Correct?

A Yes.

Q "Throughout its over two decades of clinical use, no evidence has been found to support a link between SNF permanent filter implantation and the serious health

11:15:50 consequences that have been expressed -- an expressed concern

from FDA regarding removable IVC filters."

Did I read that correctly?

A Yes.

Q Did that information ever get transmitted in an IFU or in marketing materials or a brochure or any communication from Bard that the SNF as a permanent filter did not have the same serious health consequences as their retrievable filters?

A It would not have been an appropriate comparison. This is a permanent filter, so --

Q I just want to know whether or not that has ever been communicated.

MR. ROGERS: I'm sorry, Your Honor. I believe the witness is being cut off from his response.

THE COURT: Please permit him to respond.

Go ahead.

THE WITNESS: They're two different types of devices. It wouldn't have been appropriate to compare the Simon Nitinol filter with any optional filter on the market.

BY MR. LOPEZ:

Q Without the Simon Nitinol filter there would not have been a Recovery filter, right, because that's the predicate for the Recovery filter; correct?

A I believe so.

Q And the G2 filter was, first and foremost, a permanent filter; right?

11:17:02 A Correct.
Q In fact, that's what it says on the -- on the -- in the IFU, it says it's a permanent filter.
A Yes.
11:17:09 Q And the Eclipse says that.
A Yes.
Q And Meridian says that.
A All filters at the time on the market said that.
Q So is it your testimony that if any of those devices that
11:17:23 are first and foremost permanent devices are not retrieved, that they do not have to be as safe and effective as a permanent device like the Simon Nitinol filter?
A No.
Q Did the company ever tell doctors that as a permanent
11:17:46 device our Simon Nitinol filter is safer, doesn't have the serious health consequences as our retrievable devices; if you decide that you're not going to retrieve it, and you want to leave it in permanently, take out our retrievable device and put in our safer permanent device? That message ever get out?
11:18:06 A I don't believe so.
Q Could have done that if you wanted to; right?
A Presumably.
MR. LOPEZ: 6013, please.
I'm sorry, I'm not speaking -- 6013.

11:18:43 BY MR. LOPEZ:

Q Sir, you're familiar with this document, are you not?

A Yes.

Q And can we go to page 4 of this document.

11:19:00 And, sir, this is a response to FDA questions.

MR. LOPEZ: I'm sorry. May I move -- I want to move 6013 into evidence at this time, Your Honor.

MR. ROGERS: No objection.

THE COURT: Admitted.

11:19:13 (Exhibit 6013 admitted.)

MR. LOPEZ: And may I publish?

THE COURT: Yes.

MR. LOPEZ: Could we go back to the first page real quickly, Felice.

11:19:22 BY MR. LOPEZ:

Q This is on the Meridian filter system and it's dated December 27, 2010. Do you see that, sir?

A Yes.

Q Okay. And if we can go to page 4, this is -- shows the

11:19:42 progression of these devices that were basically all borne out of the device before it; true?

A They were based on predicate devices; correct.

Q Only device missing here, or devices, would be the Simon Nitinol filter and the Recovery filter; correct?

11:19:59 A Yes.

11:20:01 Q And basically these are just re-designs of the same filter; true?
A They're product enhancements. Correct.
Q And then, in fact, it even explains what this depicts at
11:20:16 the bottom.
A Um-hmm.
Q Correct?
A Yes.
Q In 2008 BPV launched the G2 filter with an option for
11:20:24 filter retrieval; correct?
A Yes.
Q Then in 2008 a hook was added.
A Yes.
Q That would allow for snare retrieval and they call that
11:20:33 the G2 Express filter. Correct?
A Correct.
Q And that is often referred to as the G2X.
A Correct.
Q So as far as the design of the legs and the stability and
11:20:44 the strength, that new design had nothing to do with that; right? It just had to do with the hook at the top where it could be retrieved; correct?
A I'm not sure if there were any other designs at that point in time, but, yeah, I believe that's the only change is adding
11:21:00 the hook.

11:21:02 Q And then to create a smoother surface, the G2X filter was electropolished resulting in the Eclipse filter --

A Yes.

Q -- and that was cleared in January 2010; correct?

11:21:14 A Yes. Correct.

Q Then the Meridian filter was under review. This design was under review in December 2010; correct?

A Yes.

Q And it was meant to be a safer alternative design to all

11:21:27 of those devices that preceded it. Is that a fair statement?

A A product enhancement or an improvement on the design; correct.

Q Well, safer alternative design to the ones before it. Is that a true statement?

11:21:39 A I think all of the changes are designed to make it a better performing product. Every subsequent -- or easier to use for the clinician.

Q And what they did to the Meridian is they added one downward pointing titanium anchor laser welded to each filter

11:21:55 wire arm; correct?

A Yes.

Q Also looks like they did something to the feet as well; right?

A Yes.

11:22:03 Q And was that supposed to stabilize that filter so it

11:22:07 wouldn't move, wouldn't tilt, wouldn't perforate and make it more susceptible to fracture?

A I think it was just to make sure that was more securely anchored in the IVC.

11:22:23 Q Do you know how long Bard had been talking about putting anchors on their filters because of some design complications it had with the very first device that's on this evolution?

A I don't.

MR. LOPEZ: 1940, please.

11:22:47 I think this has already been admitted into evidence. If so, I'd like to publish it, Your Honor.

THE COURT: Yes, it looks like it's been admitted. You may publish.

BY MR. LOPEZ:

11:23:13 Q Sir, earlier we talked about tracking and trending, that Bard did that.

A Yes.

Q Correct?

A Yes.

11:23:22 Q And I think we're in the time period 2009 and '10 when the Nicholson study was being discussed and -- internally by Bard; right? Remember that?

A Yes.

Q And we talked about whether or not maybe Bard already had

11:23:35 that information that was being put in the medical literature

by Dr. Nicholson, do you remember us talking about that?

A About us having the information to be put into the literature?

Q Those type of problems with the G2 filter and the prevalence of those problems. Do you remember that?

A All of the -- all of the complaints with our filters are tracked. Correct.

Q This is one of those charts where Bard is tracking and trending their devices against competitive devices; correct?

A It appears to be that.

Q All right.

Let's look at this.

MR. LOPEZ: So -- before you do that, Felice, I want to orient us on time. Could you go down to the Notes section.

BY MR. LOPEZ:

Q Do you see that this is Bard data from TrackWise not MAUDE through July of 2010?

A Correct.

Q And then MAUDE and IMS data is through second quarter of 2010; true?

A Yes.

Q MAUDE data is what companies are reporting to the company or to FDA that ultimately gets into this database at FDA where you can find all of this data; right?

11:24:52 A MAUDE is an FDA database; correct.
Q And the IMS data is -- are sales data; correct?
A I believe that's sales data; correct.
Q That's how you do some rate comparisons. Even though it's
11:25:04 not perfect data, we know that, but it's the only data that exists in the IVC world because there have been no clinical trials; correct?
A IMS data are sales data; correct.
Q Let's look at what Bard is seeing with respect to its
11:25:20 performance of its devices compared to its competitors.
Do you see where fractures are broken up into Fracture A and Fracture B?
A Yes.
Q Do you know what Fracture A is?
11:25:36 A I can never remember the different types. One is where it's fractured and stays in C2 and the other is where a part of it embolizes and moves.
Q Right. So I want you to assume for a moment that Fracture A is the one that -- the worst potential consequence for a
11:25:56 patient. In other words, it actually moves into hearts, lungs, and distant organs. Okay?
A Um-hmm.
Q You see Bard here has data on its own filters and also has data on all of its competitors. Correct?
11:26:11 A Yes.

11:26:12 Q And would you agree with me that -- for example. ALM. ALM's a competitive retrievable filter; right?

A I believe it is.

Q And it had zero type A and zero type B fractures.

11:26:27 Correct?

A It looks like it has zero reported here; correct.

Q Granted it may not have been on the market very long for us to see whether or not it might have some down the road. But at this chart we know that the ALMs were zero, zero;

11:26:43 correct?

A According to this chart, yes.

Q And one of the biggest competitors to Bard during this period of time would have been the OptEase and probably the Celect; correct?

11:26:55 A I know that there are other filters that have significant market share. Correct.

Q So Bard would have known in July of 2010 that the Cook had two fractures that were reported where it embolized beyond the site of the filter and that the OptEase had zero; correct?

11:27:19 A Zero. I'm sorry. Type A fractures.

Q Right.

A Yeah, zero reported to MAUDE.

Q By the way, the Simon Nitinol filter is nowhere to be found on this comparison, is it?

11:27:32 A It's not.

11:27:32 Q It used to be, right? When they were tracking before they included the Simon Nitinol filter.
A I don't know. I'm not as familiar with this process.
Q I mean they didn't take it off here because it's a
11:27:45 permanent device because there's other permanent devices on this comparison; true?
A I don't know why it's on -- or why it would have been on there or would not have been on there. I'm not sure. I don't know what the criteria are for preparing this report.
11:27:58 Q So of all the filters that were on the market that Bard chose to compare, the total competitors, there were 13 Fracture A's where the fracture didn't stay near the filter but actually embolized into patient's hearts and lungs; true?
A What column are we -- oh, I see.
11:28:19 Yes, it appears that way.
Q And during the same period of time, there were 195 fractures like that for Bard filters; correct?
A Total. Yes.
Q And 160 type B fractures where there was a fracture but
11:28:40 fortunately it didn't embolize into the patients' hearts and lungs; true?
A Correct.
Q And all of the competitors combined had 20; right?
A So the data for Bard filters would have been everything we
11:28:53 know about our devices. Other data are extracted from a

website that has been advertised by FDA as not being reliable, so I can't make -- I can't make apples and apples comparison.

If I had their data from all their reported things, I probably could be making a more intelligent comparison.

Q I know, but this is what Bard had. Let's talk about that.

Every one of these manufacturers were under the same obligation to report to the MAUDE database as Bard; correct?

A All manufacturers are, yes.

Q You have to follow the same rules; right?

A Um-hmm.

Q And you're not suggesting to anybody that there's some rule breakers on here that my skew these numbers.

A I don't know what internal processes are for other people. I know I worked for many medical device companies and Bard has the most conservative approach of reporting every single thing that happens to the FDA. I've never seen anything like that.

Q Including the Simon Nitinol filter.

A All of our products.

Q How many type A fractures occurred in the Simon Nitinol filter as of 2010?

A I don't know.

Q How about type B fractures?

A I don't know either.

Q Well, you certainly could do a comparison there. We wouldn't have to worry about whether or not the data on the

competitors is correct, you could have done a Simon Nitinol comparison on these types of fractures to Bard's permanent devices that had the option of being retrieved; right?

A Absolutely, except it wouldn't have been an appropriate comparison.

Q When you look down at these percentages, I know these percentages here are not accurate percentages of the rate; correct?

A I don't know the math that goes into them, but their denominator is presumably the filters sold.

Q This is Bard's data they're using. And we didn't know how much underreporting may be contributing to these low percentages; right? Could be much higher than that.

A I'm not sure. It could be higher, could be lower. It's inaccurate. I mean, imprecise, I'll say that, at best.

Q A good example of that would be the adverse event data that was being reported to Bard about caudal migrations before the EVEREST data was a number under 1 percent. Remember that?

A Say that again.

Q In other words, if Bard was just doing an analysis on the adverse event reports they were getting from the field and using this same analysis and just doing -- using those numbers against sales, that number of caudal migrations was some number significantly below 1 percent; right?

A I don't know what the number was.

11:31:34 Q What we do know, though, when they did the EVEREST study, it showed that at least the ones that were counted by Bard were 12 percent or 12.1 percent caudal migrations; correct?

A And the clinical trial.

11:31:47 Q You're going to get much better data in a clinical trial.

A Sure.

Q So you have to assume that when you look at these numbers, these could be the tip of the iceberg; right?

A I -- presumably, I guess. I don't know.

11:32:00 Q So let's look at how the G2, for example, compared to -- let's look at the OptEase for type A fractures.

MR. LOPEZ: One more over, one more column over.

That's okay.

BY MR. LOPEZ:

11:32:29 Q So there's zero there. So let's assume for sake of argument there were -- the number was .001 in OptEase. They just missed one; it should have been 1.

If it had been 1, would you agree that the Bard G2 filter's 54 times more reports of that type of fracture to the

11:32:54 FDA's database than the OptEase filter?

A I can't talk about how many reports to the FDA. The numbers are very different here but, again, I didn't generate this analysis and I don't know exactly where the OptEase information came from.

11:33:10 Q The Cook Celect, .004 percent, recognizing these are just

11:33:15 percentage of being reported, comparing that to -- let's just combine all of the Bard filters -- Recovery, G2, G2X, Eclipse -- 96 times more likely reported rate of that type of fracture. Correct?

11:33:37 A The number is 96 times the other number.

Q Right. And just looking at this, Dr. Nicholson was right, there is a prevalence of those types of fractures in a G2 filter. Correct?

A No.

11:33:56 Q Did you ever go to FDA in 2010 and say, by the way, we've been doing exactly what you've expected us to do, we've been tracking and trending our devices and we are significantly more dangerous when we have a fracture migrating to a heart or lung than any other device on the market?

11:34:18 A We presented all of the comparative data directly to the FDA --

Q I'm asking whether or not you made that statement to Bard, what I just said.

MR. ROGERS: Your Honor, I believe the witness is

11:34:28 being cut off from his response.

THE COURT: Please allow him to finish.

MR. LOPEZ: I thought he was, Your Honor. I apologize.

THE WITNESS: We presented all of the data on

11:34:35 comparative analysis in a face-to-face meeting with FDA and

11:34:39 disclosed everything, as we had all along to them.
BY MR. LOPEZ:
Q Let me ask you, was this data provided to Mrs. Hyde?
A I don't know what was provided to anybody, sir.
11:34:50 Q Do you think Mrs. Hyde expected that when she got a G2, G2X, or Eclipse filter that that filter put her at the type of increased risk of a fragment going to her heart as displayed by this internal trending document from Bard?
A I believe --
11:35:10 MR. ROGERS: Objection, Your Honor. 602. 403.
THE COURT: Overruled.
BY MR. LOPEZ:
Q Sir?
A I believe Mrs. Hyde or any other patient receiving a
11:35:17 medical device would expect that device would be something that would save their life or help their life.
Q I'm not asking you whether or not -- don't you think she had the right to know that Bard internally had risk information that showed a prevalence over every other device
11:35:32 on the market, including its Simon Nitinol filter, of a fracture migrating to her heart or lungs? Don't you think she had a right to know that?
MR. ROGERS: Objection, Your Honor.
THE COURT: Hold on.
11:35:43 What's the objection?

11:35:44 MR. ROGERS: Objection is relevance, 403, and 602.

THE COURT: Sustained on relevancy.

BY MR. LOPEZ:

Q The data and comparisons here were never presented to
11:36:00 patients who were going to make the final decision whether or not they were going to agree to a Bard device, whether it be G2, G2X, or Eclipse, to potentially other devices that may have been available to him or her; true?

MR. ROGERS: Objection, Your Honor. Same objection.
11:36:19 Same basis.

THE COURT: Overruled.

THE WITNESS: The data that are presented to patients are included in IFU's or patient brochures. FDA is the leader and the guide on what is presented to patients.

11:36:31 There is a ton of information here. I really don't know where it came from. And I think you have to be really careful on what you interpret and what you present to people because at the end of the day, you're -- you have to make an appropriate comparison and make sure it's accurate.

11:36:48 BY MR. LOPEZ:

Q Well, I want to make sure you are not suggesting that the book -- FDA does not condone companies making false and misleading representations about their devices to consumers; true?

11:36:59 A Absolutely not.

11:37:00 Q And the FDA doesn't condone companies from letting patients know when they have a device that might be increasing the risk of a known complication because of the design of their device; true?

11:37:12 A The FDA would not condone that; correct.

MR. LOPEZ: Those are all the questions I have, Your Honor.

THE COURT: Cross-examination.

MR. ROGERS: Your Honor, I don't have any questions for Mr. Van Vleet at this time, but we reserve the right to call him back in Bard's case in chief.

THE COURT: All right.

You can step down, sir.

MR. O'CONNOR: Your Honor, at this time we called Mr. Chad Modra.

11:37:53 THE COURTROOM DEPUTY: Sir, if you'll please come forward, stand right here, raise your right hand, please.

CHAD MODRA,

called as a witness herein, after having been first duly sworn or affirmed, was examined and testified as follows:

D I R E C T E X A M I N A T I O N

BY MR. O'CONNOR:

Q Good morning, Mr. Modra. My name is Mark O'Connor again. How are you doing today?

11:39:06 A Good.

11:39:07 Q You're employed by Bard?
A I am.
Q And you are currently a continuous improvement leader?
A That's correct.
11:39:15 Q There was a time when you were the vice president of quality assurance at Bard Peripheral Vascular?
A Yes.
Q In that capacity you oversaw quality assurance, field assurance, and other departments; true?
11:39:28 A That's correct.
Q Your responsibilities in that position was post-market surveillance; correct?
A Among many other things, including post-market; correct.
Q You oversaw regulatory obligations with Bard; true?
11:39:46 A I did.
Q You didn't see -- oversee regulatory obligations of Bard in terms of handling complaint record detail reports?
A Yes, I did.
Q Okay. Thank you.
11:39:57 So you were responsible for handling complaints and the complaint process at Bard; true?
A True.
Q MDRs are medical device reports; correct?
A Correct.
11:40:11 Q And you have been produced by Bard in various depositions

as the person most knowledgeable about how complaints are handled within Bard Peripheral Vascular; correct?

A Correct.

Q You are also knowledgeable about Bard IVC filters; fair?

A Correct.

Q And the IVC filter department within Bard is in Tempe, Arizona; is that right?

A The research and development and quality assurance area is here; correct --

Q And --

A -- Tempe.

Q -- are you still located in Tempe?

A I'm located in Phoenix. Yes.

Q Now, just so we have an understanding of complaints, Bard was responsible to investigate every type of complaint that came in regarding devices, including filters; true?

A That's correct.

Q And the way that Bard received complaints could be from doctors; correct?

A Doctors as well as sales reps. Any number of -- from anywhere, virtually.

Q Point is, there's a number of different ways and a number of different sources who could report complaints to Bard; right?

A Yes.

11:41:28 Q And regardless whether it was a sales rep or doctor, Bard had the responsibility to investigate the report; correct?
A Correct. That is correct.
Q And it was the sales representative of Bard that had
11:41:41 ongoing contact with the doctors; true?
A They do. That's correct.
Q You understood that sales representatives develop relationships with doctors who use Bard products; true?
A True.
11:42:00 Q Now, if a doctor notified a sales representative of a problem with a filter, that would initiate the complaint development process; fair?
A The complaint investigation process. Correct. Because we'd become aware of it at that time.
11:42:17 Q And then the complaint handling process would go to field assurance at Bard Peripheral Vascular?
A That's correct.
Q And from there Bard would engage in a standard process to investigate each and every complaint.
11:42:34 A That's correct.
Q And then Bard would investigate the complaint and then eventually put the complaint information in what is called a MDR or complaint detail report; is that -- record detail report.
11:42:49 A We would investigate each and every complaint and then if

it rose to reportable, then it would be reported as an MDR.
Q And that's something that would be done in the regular course of Bard's business; fair?
A Yes. Correct.
Q And do you agree, Mr. Modra, it was important for Bard to be accurate and thorough to every extent possible in the investigation, to learn all important information that would eventually go into the reports and complaint files?
A Correct. We'd make many efforts to get as much information as we could.
Q And Bard would confirm or verify the report knowing that it was important to submit the reliable information to the FDA; correct?
A Based on the information we're able to obtain, yes. We would make that determination and submit it as required.
Q And since 2003, complaint investigations at Bard had been formed and medical device reports have been completed at Bard; is that true?
A Yes.
Q And the investigations were, for among other purposes, to complete medical device reports, MDRs is what they're called; true?
A That's one aspect. They would be investigated to be fully investigated so we could track and trend them and complete the MDRs.

11:44:38 Q Right. So MDRs is one reason that you do the complaints thoroughly and accurately, and the other reason is to track and trend at Bard; correct?

A Of course.

11:44:48 Q Track and trend failures of devices? For example, filters?

A Product experience, failures, environment that it was used in, placement, patient condition.

Q And the process starts with gathering information from a

11:45:07 complaint detail report; true?

A It begins from the communication from the patient, from the customer.

Q Okay. So eventually it comes in to Bard, somebody at Bard is responsible to gather that information, put it in a written

11:45:23 form, and then it goes into the complaint process; correct?

A That's correct.

Q And the complaints are maintained by Bard and also reported to the FDA; fair?

A Correct.

11:45:36 Q And you have a data system -- is it called TrackWise?

A TrackWise, yes.

Q You use the information from those complaints so that you can track and trend; correct?

A Correct.

11:45:47 Q So you have the ability, for example, if somebody wanted

11:45:50 to know within a period of time how many devices fractured, failed, and embolized to a different part of a patient's body, you could look in your database to find that.

A All the information that was reported to us would be in there; correct.

11:46:02 Q So, in other words, you can -- you have the ability to look at the complaints that have been reported to you and that have been taken and put into reports at Bard and determined, for example, how many fractures a certain filter has shown over a given period of time; correct?

11:46:20 A Correct. Based on the input information, yes.

Q All right.

MR. O'CONNOR: Felice, could we show Exhibit 3292.

BY MR. O'CONNOR:

11:46:47 Q Now, Mr. Modra, do you recognize this? It looks like it's actually a jacket or folder that is in the MDR part of Bard.

A It says MDR on it. We don't have the paper files. We have them in the database. So it looks like maybe it's --

Q Can we go to the next page, please.

11:47:09 A -- a cover.

Q This is a Complaint Record Detail Report in the form that's used by Bard; correct?

A Yes.

MR. O'CONNOR: Move to admit 3292, Your Honor.

11:47:20 MS. HELM: Objection, Your Honor. 401, 403, 802,

and this also violates the Court's prior ruling on this document.

THE COURT: Well, to address all of those I think we need to talk about it. We could do it at sidebar. We've got 12 minutes left. Do we need to do that before you go on, Mr. O'Connor, or can you cover other things?

MR. O'CONNOR: Well, this is the point I'm going to cover it, Your Honor.

BY MR. O'CONNOR:

Q You're familiar with this type of form; correct?

THE COURT: Well, we need to talk if you want to talk about this. Let's talk at sidebar.

(Bench conference as follows:)

THE COURT: Would you explain the objection, Ms. Helm.

MS. HELM: Yes, Your Honor. It's a complaint file that contains a significant amount of hearsay. In Jones -- and I understood you this morning to say you were going to stand by your prior ruling on complaint files on the MDRs and the summary. In Jones you did not admit any complaint files, you only admitted their 1006 summary and one monthly management report.

So I'm following your direction from this morning as to what was admitted in Jones. And this document has -- it -- it's full of hearsay. There's no evidence it's

substantially similar to the incidence in this case; has no relevance to it.

Again, I'm following your direction from this morning as to where you said you were going to get on this based on your ruling in Jones.

MR. O'CONNOR: Well, I don't think it is hearsay. I think it's information they're required to gather and they put in the form called a complaint and it's done in the ordinary course of business at Bard. And the ones I want to show him are going to have to deal with fractures of the Eclipse, the G2, and the G2X. And fractures that go to other parts of the body, including the heart and lungs. It's going to be the same information we gave in summary form. I have about ten of them I want to go through with him.

THE COURT: 10 complaint files?

MR. O'CONNOR: Yes.

THE COURT: Were they previously admitted in the previous trials?

MR. O'CONNOR: No, I don't think so because I think they're probably of a different type for this. I think there's different ones. I don't recall if they were admitted in trial. What we did in trial, we tried to get in the complaint summary. I don't think -- I don't recall your ruling yes or no if a complaint file came in.

THE COURT: Is your objection hearsay within

11:50:07 hearsay?

MS. HELM: It's -- yes. It's hearsay within hearsay. It's also relevance and a 403 objection. And --

THE COURT: Well, let's stick with hearsay for a

11:50:17 minute.

Are you objecting to the Bard-created information in the file as hearsay or just the statements of doctors or patients or others that are reflected in the file?

MS. HELM: The latter, Your Honor.

11:50:30 THE COURT: Okay. So it's a hearsay within hearsay objection.

MS. HELM: In addition to the -- yes. In addition to the other objections.

THE COURT: On the hearsay issue.

11:50:38 MS. HELM: On the hearsay issue that's what it is, but I have other objections.

THE COURT: I understand.

What's your response on hearsay within hearsay?

MR. O'CONNOR: These are documents so I can't

11:50:47 identify in my mind what exactly they're talking about. I think there are some medical records that are attached. I certainly think we can admit the relevant portions where it's information gathered by Bard that identifies what they learned about the failure, where it went in the body, the

11:51:02 type of filter, the data and then whether there was a root

11:51:07 cause analysis done.

THE COURT: So you want to introduce ten of these complaint files; is that right?

MR. O'CONNOR: Yes, sir.

11:51:14 THE COURT: The witness said he didn't recognize it; it's not kept in Bard in this form.

MR. O'CONNOR: No, that was the folder. I just got him to recognize the next page.

THE COURT: Well, you got him to recognize the form; 11:51:23 right?

So are you intending to introduce everything that's if the folder?

MR. O'CONNOR: No. Just parts. To show what that particular complaint file shows. For example, G2 fracture 11:51:36 that went to a heart or lung.

THE COURT: I don't know if that's hearsay within hearsay without seeing it. There's a hearsay within hearsay objection.

MR. O'CONNOR: Okay. Well, we can go to specific 11:51:52 sections that he talked about in the last trial and --

THE COURT: Of this complaint file?

MR. O'CONNOR: Well, complaint files in general. If you're going to allow us to prepare a summary, we can do that. But last time we talked about him about complaints, 11:52:07 how they're done, and then we put together a summary from

those complaints in which he agreed, I think, that the complaint summary had information that could be used and was used in other parts --

THE COURT: Right. I dealt with this in detail and issued an order saying exactly what was going to come in. There was a 1006 summary. And then I allowed some representative MDRs. I don't have that order in front of me, but I think I need to review that and see exactly what you're going to submit to know if this is consistent with the order.

MR. O'CONNOR: Okay. Then I'll go to a different area to wrap it up in about five minutes and then we can talk about that and come back --

MS. HELM: Your Honor, Docket 11157.

THE COURT: Do you have a copy?

MS. HELM: I can get you one and have it to you by the lunch break.

THE COURT: Okay. Thank you.

(Bench conference concludes.)

THE COURT: Thank you, ladies and gentlemen.

BY MR. O'CONNOR:

Q Mr. Modra, in general, the Complaint Record Detail Reports include a section called -- entitled Complaint Information; is that right?

A Complainant information?

Q Yes.

11:54:00 A Correct.
Q And that is a place where the information that -- that is information that Bard employees are responsible to collect in the course of the investigation when following Bard
11:54:13 procedures; is that correct?
A Correct.
Q And then investigations at Bard are conducted by quality engineers with engineering degrees; true?
A Correct.
11:54:31 Q And your charge, your direction to those engineers and to Bard employees is to get as much information as they can about the event; correct?
A Correct. And to document it.
Q And you also have employees from research and development
11:54:46 and manufacturing who are also involved in the investigations; correct?
A Correct.
Q And so you -- you're directive to all those people is to get as much information as you can and document it.
11:54:58 A The person who's responsible for getting the information is typically the field assurance representative. They get all that information from whoever's reporting the event and then it's analyzed by those other functions.
Q The -- a reason it's important to involve engineers and
11:55:16 employees is for accuracy and completeness of the reports;

correct?

A For analysis of the information. That's correct.

Q And it's important for the reports to be accurate and complete because those reports are not only used to go to the FDA, but they're also used internally at Bard; true?

A Correct for tracking and trending.

Q I was going to ask you that.

So one reason you use these reports at Bard is for tracking and trending; correct?

A That's correct. Analysis of what the issue was and for product improvements.

Q And if we just -- in the Complaint Record Detail Report, there's also a section that is entitled Event Description; is that correct?

A Yes.

Q And what generally goes into event description?

A The narrative of what occurred. So when it is communicated to us, we ask a series of questions and we get, you know, who's performing the procedure, what was the result, is the patient okay, is the product performing as you expected, what did you observe, what did you see, at what time did any issue occur.

Q And the event description is information that can be used by Bard in other internal documents; correct? It's a summary.

A It's a summary of the narrative of what was communicated

in -- to us.

Q And that summary is used by Bard in other reports, other documents, and also used in tracking and trending; correct?

A That summary itself isn't for tracking and trending. A better way to do that and the way we do that is product failure codes.

Q The information in summary is used for an MDR.

A It's reported in MDRs. That's correct.

Q And also in the investigation in the complaint reports is a place where people responsible for the report are to indicate whether a root cause analysis was done; correct?

A Correct.

Q And a root cause analysis is an analysis that Bard is required to conduct to identify possible causal factors of a filter failure; true?

A Correct. What was the root of the issue.

Q So you define the issue, analyze, and then take steps to prevent. That's what root cause analysis is for; correct?

A Use a number of tools, investigative tools, to get to that and then determine what the root cause is. That's correct.

Q So Bard is required to look at each event and determine whether there is a root cause analysis that should be conducted; fair?

A Correct. If possible. And in some cases there isn't enough information to be able to get to that.

11:58:40 Q And root cause is an important responsibility at Bard; correct?
A That's correct.
Q It starts -- it's a process that starts right at the
11:58:49 complaint investigation part of receiving a complaint; fair?
A That's correct.
Q And it's an obligation that Bard has; true?
A True.
Q And Bard can use that root cause analysis for a number of
11:59:10 internal reasons; fair?
A Primarily to determine what the issues are, if there's any that we can affect. Correct.
Q You can use a root cause analysis to determine whether there's a problem with a design of a filter and it's leading
11:59:25 to failures and creating a risk of harm to patients; true?
A True, amongst other root causes: Use, environment, clinical situations.
THE COURT: All right. We're going to break at this point, ladies and gentlemen.
11:59:39 We will resume at 1 o'clock. Please remember not to discuss or do any research about the case. And we will see you at 1:00.
(The jury exited the courtroom at 11:59.)
THE COURT: You can step down, Mr. Modra.
12:00:20 All right. Counsel, as of lunch plaintiff used 2

12:00:22 hours and 42 minutes this morning. Defendants have not used any yet.

MS. HELM: I'm sorry, Your Honor?

THE COURT: 2 hours 42 minutes for plaintiff as of 12:00:32 the lunch hour. That gets added to their time. I haven't done the addition yet. Everybody can do that.

So there are some things you all wanted me to look at over the lunch hour?

MS. HELM: Your Honor, while she's coming up, Docket 12:00:46 Number 11122 was actually your first order.

THE COURT: I've got them both. 11157 and 11122.

MS. HELM: And then there's actually an additional order: 11256.

THE COURT: Okay.

12:01:02 Could you print that, Traci.

All right. I'll look at those over the lunch hour. But I would ask you to do the same. Because that's what I'm going to do with respect to what comes in. And I was fairly specific in 11157 as to what could come in as a result of 12:01:19 Mr. Modra's testimony.

MR. O'CONNOR: We'll look at them.

THE COURT: Okay.

Mr. Lopez, you said there was a second matter you wanted me to think about over the lunch hour?

12:01:41 MR. LOPEZ: They both had to do with deposition --

12:01:43 MS. HELM: She's only shown me one.

MR. LOPEZ: You know about the other one, Ciavarella.

MS. SMITH: This bottom portion is in evidence and 12:01:59 this is what's being argued about. I just highlighted the two places they're objecting to in the transcript.

THE COURT: Okay.

So I will look at this transcript and we will see you at 1 o'clock.

12:02:14 MR. ROGERS: Thank you, Your Honor.

MR. LOPEZ: Thank you, Your Honor.

(Recess taken at 12:02 p.m.)

(End of a.m. session transcript.)

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C E R T I F I C A T E

I, PATRICIA LYONS, do hereby certify that I am duly appointed and qualified to act as Official Court Reporter for the United States District Court for the District of Arizona.

I FURTHER CERTIFY that the foregoing pages constitute a full, true, and accurate transcript of all of that portion of the proceedings contained herein, had in the above-entitled cause on the date specified therein, and that said transcript was prepared under my direction and control, and to the best of my ability.

DATED at Phoenix, Arizona, this 26th day of September, 2018.

s/ Patricia Lyons, RMR, CRR
Official Court Reporter